HIT Standards Committee
Final Transcript
March 29, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you operator. Good morning, everybody, and welcome to the 23rd meeting of the HIT Standards Committee. This is a Federal Advisory Committee, which means there will be opportunity at the end of the meeting for the public to make comment, and there will be a transcript posted on ONC's Website. Just a reminder for committee members to identify yourselves when speaking since the meeting is being transcribed.

And let's do a quick introduction around the table beginning on my left with Doug Fridsma.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
This is Doug Fridsma from ONC.

John Klimek – NCPDP – VP Industry Information Technology
John Klimek, NCPDP.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Karen Trudel, Centers for Medicare & Medicaid Services.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living, representing long-term post acute care.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie, Cerner Corporation.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff with Intermountain Healthcare and the University of Utah.

Judy Murphy – Aurora Health Care – Vice President of Applications
Judy Murphy, Aurora Health Care.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Walter Suarez with Kaiser Permanente.

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
Farzad Mostashari, ONC.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good morning. Jon Perlin, HCA, Adjunct Faculty at Vanderbilt.

John Halamka – Harvard Medical School – Chief Information Officer

John Halamka, Harvard Medical School.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker, Geisinger Health System.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenet Healthcare.

Marc Overhage – Regenstrief – Director
Marc Overhage, Siemens Healthcare.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Nancy Orvis, Department of Defense.

Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect
Anne Castro, Blue Cross Blue Shield of South Carolina.

Cita Furlani – NIST – Director
Cita Furlani, NIST.

Martin Harris – Cleveland Clinic – Chief Information Officer
Martin Harris, Cleveland Clinic.

Judy Sparrow – Office of the National Coordinator – Executive Director
And, do we have anybody on the telephone? Dixie Baker, are you there?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm here. I'm Dixie Baker, SAIC.

Judy Sparrow – Office of the National Coordinator – Executive Director
Right. Anyone else on the telephone? All right, with that, I'll turn it over to Dr. Mostashari.

Josh Lemieux – Markle Foundation – Director Personal Health Technology
Josh Lemieux with the Markle Foundation in the place of Carol Diamond. Sorry.

Judy Sparrow – Office of the National Coordinator – Executive Director
Sorry. Thank you, Josh.

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
Good morning. Welcome, those here and those on the phone. I'm Farzad Mostashari. I'm sitting in for David Blumenthal, who is leaving us, as you all know. And who has really helped set a legacy, I hope, for the work that we all have undertaken in the past two years in the design and launch of the programs and policies that came out of High Tech.

One of the kinds of bittersweet aspects of this time has been that it's been a time for taking stock of what we've accomplished together, and what remains to be accomplished, which is formidable. I think it's been gratifying for us at ONC, and the staff at ONC, that overall as people have been reviewing how far we've come and the way we've gotten here, there seems to be broad agreement among the key stakeholders, among the provider community, among the policymakers, consumer groups, and many, many others that we are on the right track. We have the right basic approach, we have the right policies and strategies, and as the Secretary, Secretary Sebelius said, at HIMSS, we want to continue down the path. We want to keep moving ahead in direction consistent with the direction that we've been moving.

And I think as we move towards from strategy to execution on many of the things that we have started and designed, that's going to be important for us to keep in mind. But we also recognize that there will be new challenges, that nothing stays still; certainly not health IT. So, when we look at the health IT strategic plan, there are areas there that we identify as being key areas for moving ahead for a consumer eHealth, for a learning healthcare system, for example, while we continue to execute on kind of our core work to date around adoption, exchange, privacy and security.

So, when we move ahead, what does it mean for us to stay consistent with a strategy that we've had so far? I think it means staying consistent to the principles that got us here; the principles of openness and transparency in our processes. That's what this is. That's what this is at a critical part of that tendency that we bring to how we do our work.

It's about keeping our eye on the prize and being ambitious, being bold, knowing what it is that we are striving for, which is improved health and healthcare. That it's not the technology, it's the technology and the service of where we want to go. And always being pushing, pushing and driving towards that ultimate goal. But also having it be achievable, having our feet on the ground, knowing what's actually happening in the real world, monitoring and adapting to conditions, being evidence-based.

It means fostering innovation and using the marketplace and the energy that comes from the market and industry while making sure that we watch out for the little guy. Watch out for market failures and information asymmetries, and help guide the context within which the market operates. And it means, most importantly, putting patients and their interests in the center of everything that we do; their interests, including privacy and security.

So these are the principles that have guided us. These are in some ways the most lasting, I hope, legacy of David's time with us. And those are going to be what are going to inform and are going to enlighten our actions as we move forward together.

There's going to be a tremendous amount of work for this committee in the next two quarters; in this spring and summer. As we look at the rule making calendar, there's—and then there's going to be a tremendous amount of work for our staff—on the reg writers—in the fall, working with CMS on three regulations. One around, obviously, meaningful use, stage two; the parent certification criteria and standards; and then also governance rule.

There's a tremendous amount that has to get done relatively quickly, and a lot of the policy committee workgroups are going to be feeding this committee their use cases. There's going to be from the meaningful use workgroup recommendations that come from the PCAST workgroup. There's going to be options around, particularly metadata and universal exchange language that this group will need to quickly process and we need to seek public input on—additional public comment on. Quality measures, my goodness, there's going to be a whole lot of work having to do both with the vocabulary sets, code

sets, as well as specifications for the quality measures. Whether it's around lab results, public health, transitions of care, transport protocols, certificates, directories—my goodness.

It's going to be an intense period and I think we really just want to say, again, we couldn't possibly do it without you. And we thank you for your service. We will try to always be better. We'll try to improve continually. We know that we can improve. We know that there's always room for improvement, and I think there's plenty of room for improvement in whether it's our policies, our programs, our processes. And we look to you to help us. We look to you for feedback, and for your partnership. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you very much, Farzad. Dr. Mostashari has a very daunting responsibility to provide guidance to the Office of National Coordinator during a period where the action is not slowing down. Indeed, it is picking up. I want to thank you for taking on this responsibility along with Doug and other members of the team.

It is a great privilege for John Halamka and myself to be here with you. Not only because we get to share in the process with the public and share intellectual activity that but really is pretty goal directed toward improving healthcare. In fact, improving health, improving care, and improving the value of healthcare. But, it's quite remarkable, as we have conversations that you just alluded to to really develop or identify standards that's worth the aspirations of second stage and meaningful use.

It's quite remarkable to contemplate where we began, and the work going on around us. This committee has met now for over two years. Judy—what meeting number is this? 23. And if you think back, that's a lot of times to get together, but each one of you has tentacles to a world outside, and the public reminds us just how much activity is going on; the public discourse that you've alluded to, which provides insight not only into mark in progress, but identifying opportunities for improvement.

John and I, we'll come up—we'll share an idea about an area that's destined for improvement, but for the moment, I want to really focus on the amount of progress. Think back to that first meeting. Think back to the arrow on the page, which essentially identified them to use the Donabedian framework structure process outcome, the idea that policies would be reticulated, they would set the stage for the presence of information technologies that then would be implemented to the degree that there was a process in place, all culminating in outcomes.

Right now, we're in a point where there are those that have actually moved towards the further end of that spectrum, and are using those systems far greater extent than was occurring at the outset. Not just to have those systems in place, not just to use processes, but actually to work on improving the value of health performance. The value of ... care outcomes. That is quite remarkable.

It's, of course, not ubiquitous yet, and that speaks to the second and third stages of meaningful use; the distinct need for elaborating interoperability and exchange. But that is quite remarkable, and when I think of the possibility and the prevalence of electronic health information systems and the interoperability capacity that exists today that did not exist two short years ago, it's quite remarkable.

Is it completely inclusive? No, it's not yet. The mechanisms for engaging with patients, wherever their environment, are not fully elaborated, and that's part of the scope that's then is made possible by the exchange capacities and the interoperability spread further. But it's quite a remarkable achievement.

And I say this because I agree wholeheartedly, Farzad, with your introductory comments, and then the recognition, and offer that as really attribution in part to you all for your hard work. But we feel, John and

I, that we would be remiss if we did not recognize the leadership, the dedication, the intellect, and the wisdom to engage in the work, in the conversations, easy and more difficult in the political process, in the public process to really move a platform for better healthcare forward.

And so I hope you'll join me in taking a moment to, as the committee, formally recognized the leadership of Dr. David Blumenthal. And if he were here with us, he would absolutely add, "and the team" for all the accomplishments, the leadership, dedication, intellect, and wisdom to help advance the safety effectiveness, efficiency, and, indeed, the compassion of healthcare.

M
So moved.

W
So moved.

M
All in favor?

Jonathan Perlin – Hospital Corporation of America – CMO & President
If the reporters who do such a terrific job with the capture the committee would convey that motion for the record, that we thank you, as well, for your work, and the committee for that resolution.

There's a lot of work ahead, and it's interesting. Not a conversation with any colleagues in our field, certainly any colleagues on the committee goes by without discussion of where you are at vis-a-vis stage one, and what do you think is coming in terms of stage two? And what does that mean in terms of the standards that this committee will have to help enunciate, identify, and support? And so we have a very full agenda today, and a full plate of work to realize the aspirations completely that were set out.

A number of important topics on the agenda, and then we'll look very much forward to Doug's discussion of certification standards and the notice of proposed rulemaking for stage two to work, but Farzad identified in terms of the work that is necessary to prepare these regulations from staff with the input from both policy and standards committee to the various pieces. Direct project live implementation final review is important in terms of driving toward that interoperability.

And I appreciate and want to recognize the new chair of the clinical quality workgroup, Jim Walker. Walker is providing terrific leadership and then I appreciate your taking that on with Karen Kmetik. Karrie Kmetik is the co-chair and this is a challenging space. And it really gets to that third part of the structure process, the outcome. It gets to the outcomes. And it gets to a convergence of the complexity of trying to describe the world around us in a manner which can be coded, and a manner which captures the drives—the value that is sought.

As in a trust framework, they're a fabric. There is no capacity to go forward. Dixie Baker and Walter Suarez will bring forward some new recommendations as well as the clinical operations update from Jamie Ferguson and John. And then a hearing yesterday on implementation workgroup, then we'll wait for Liz and Judy, thank them for their leadership in bringing forward observations about the state of engagement and supports to really make more practical and more efficient the work of implementation.

One of the things that I know John, who will want to mention his introductory comments, is that then it is impossible to be working on stage one without contemplating the processes certification. One contemplates that process if they're in space of a vendor. One contemplates that process if they are a

provider. One contemplates that process if they are using a certified electronic health record in the aggregate, and one certainly contemplates that process if one is weaving together the functionalities required in meaningful use using multiple modules.

And I think Dr. Mostashari was very direct, and Doug and team have been incredibly supportive and look forward to your thoughts on this. But, we've learned a lot during the first go round of the certification process. We've learned that sometimes the literal transcription of policy and standard can lead to a divergence from the policy intent.

So how do we improve? We'll have some very clear examples of that. If one if putting together multiple modules to meet the requirements of the stages of meaningful use, and just arbitrarily if one covers three elements and three criteria; another covers three criteria, and they're different criteria, does that equal six criteria? Well, there's some ambiguity. There are pieces where frankly there might be philosophical differences and certification that could potentially lead to different outcomes in the certification process.

And this seems to be a good time to take stock of that process with the idea that from a standards perspective, I'll be very clear on that point, that the standards are most supportive, or that the certification process really tests for the standards and the intent of the policy and is efficient—and efficient; not inefficient, as an efficient process as possible. And that's a pretty tall order.

John, you have some—you introduced this morning, and welcome your introductory comments. You have some very specific examples of this sort of way in which this can be brought forward in the context of really making a process that has proven itself very well out of the gate even better as we go forward into more complex aspirations of stage two.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Thanks very much, and good morning everybody. I, too, want to applaud all of the accomplishments of ONC. I was looking at my calendar yesterday, and I was thinking back July of 2010 I was actually standing on a peak somewhere in the Eastern Sierra without a care in the world.

And then I look at everything that's happened from July 13th when the final regs came out to today, and it's been a rollercoaster. I mean an unbelievable amount of progress, as you described. And sure, there have been triumphs and tribulations along the way, but you look at the trajectory and not the absolute position, and what I'm seeing just among our own physicians is an amazing acceleration of adoption of healthcare IT.

So, one good thing is before David walked out the door, he presented an 81 page strategic plan outlining the Federal Healthcare IT Strategy 2011-2015. I highly recommend you all review that, because it does include a look at stage one, stage two, stage three ideas and principles as you've articulate it, but also brings into PCAST, and the notion of a learning healthcare system, and some of these goals that you've articulated that are more healthcare reform aligned. So it's a rich document with quite a lot of clear guidance broken into very achievable and measurable accomplishments.

So I think ONC may go from the office of no Christmas to the office of no summer, but at least we know where we're going. And so since we have a strategic plan, and we also now have what is going to be an imperative of getting to stage two, we need to make sure we all understand the work plan for all of our committees. So what I hope as we go through each of our areas today, and we look at clinical operations, and quality, and what's going on implementation workgroup, and security, privacy, we understand exactly what is going to be required of us because we want to ensure, given the very tight deadlines, that we have high quality work products that support all of your work.

And to the point that you made about lessons learned, I've gone through certification of a hospital—that was in January—and I've gone through certification as an ambulatory provider—that was last Friday—so I personally have gone through every single word of every single regulation and every single script in exhaustive detail to achieve certification for thousands of individuals. And what you could say is the intent from the policy committee and the standards committee was all good, and the scripts were a really valiant effort, and in now testing them in the field, there's polish that could be placed upon them to reduce burden.

And so some simple examples of that, a script may require—because the script is quite strict—the prescribing of a medication that the FDA banned two years ago and isn't available in the marketplace. So, that's something that only a clinician testing it in the field would know, because actually these meds have been around for many years. In fact, anyone who is a lay person and has asthma says, "Oh, yeah, yeah, I know about that med." Of course it's very familiar, it's just turns out when the FDA decided that CFC propellants were no longer desirable for the ozone layer that they banned a whole class of medications you can no longer write for them. So a simple example.

Or, when you reflect on some of the things that are in the regulation that we all put there. I mean, you wrote them, but we all said they should be there. But were they testable? So, certain aspects of security are exactly right, but hard to test. So how do you visually demonstrate to a tester encryption? I mean, other than turning a human, readable sentence into a bunch of binary gibberish, is that really a testable condition? And how might you reflect on a script?

Well, I'll give you an example. NIST puts up a Website and says, "Upload a file to this Website." And the fact that you could upload a file to the Website is a testable demonstration of your capacity to use this secure connection. I mean, that would be very useful. And so we didn't have that kind of test bed.

And so, as I went through every one of these scripts, what you found was you could, without changing policy, just refine these things to reduce the burden on vendors, and hospitals, and ambulatory clinics. And I think that's the purpose of what we want to do, is this is just an opportunity to learn and improve. And I, of course, will list, and my folks will list out all the areas that just subtle changes could have made so much of a difference.

So as I look at the agenda today, again the work plan we want to really hear about what it is we're going to be doing for stage two. That's going to be important. As we review the final Direct presentation here about the ecosystem and how Direct has been put into production, what lessons learned, we'll have an opportunity for a final blessing and comment. Direct is live at Beth Israel Deaconess, as I mentioned at the last meeting, and so we have been able to send transactions with my health record from Beth Israel Deaconess to Microsoft and demonstrate that it was very straightforward to put up that infrastructure quite rapidly.

I look forward to the work of the clinical quality workgroup and trying to, again, as the spirit of reducing burden, accelerate our progress and measuring quality—an important policy goal, but also to try to reduce some barriers. Jim made the most extraordinary suggestion at our last meeting, that all exclusionary criteria and quality measures be made optional. Because to be honest, the reason they're there is to make you look better.

And if you decide on a cost benefit analysis that gathering comfort care measures on every single patient isn't worth the refinement of the quality measure, that should be a choice that is left to the institution. And, as I implemented all of the quality measures, both ambulatory and inpatient, there were some

significant workflow changes required for those exclusionary criteria, which on reflection, I would have not necessarily implemented because it affects one patient out of a million once a year, and it doesn't materially impact the measure that we would want to report to CMS. I look forward to that work.

Again, we'll hear the very important digital certificate report out with some recommendations on some policy questions, as well as some technological standards to regularize the way we use certificates, and talk about next steps on provider directories. On clinical operations, yesterday we had the all-day device hearing, and there is a series of good lessons learned. Some policies, some technologies, some business model, to ensure that we can get good device standards—probably be increasingly important as we look at stage two, stage three in healthcare reform with homecare devices.

And then we will be reflecting on the improvements, and the process, and the refinement of the scripts that we already discussed. So, it should be a very good day, and I look forward to planning out the meetings for the rest of the year so we know exactly how we get to stage two from here.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, John, and so does Judy Sparrow for keeping us all in pace. Along this line, she's looking at me; did you forget the minutes again? No, I haven't. I hope everyone has had the opportunity to review the minutes and appreciate the great work of the ONC staff in recording. Any amendments onto the minutes? Any corrections?

If not, then we'll take that as consensus on the minutes and move forward into the body of today's meeting and turn over to Dr. Doug Fridsma and Arien Malec. Doug, I believe, first, to really begin to connect the dots on the path forward, stage two. And the context that John Halamka provided, as part of that forward path.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Well said, good. Thank you, Jon and John for that introduction and review of the agenda. What we've got over the course of the—we've got two hours this morning to talk about certification and standards as we look towards stage two, as well as to talk about the Nationwide Health Information Network and Direct and kind of give you an update on some of the current things that are there.

I don't have a long presentation, in large part because I hope that this just serves as a starting point for discussion. In terms of some of the things that we think need to be done over the course of the next few months, as we look towards the NPRM. In some sense, I'd like to give you some situational awareness of what the timelines are and kind of what we need to get accomplished. And then see if we can't begin to drill down and think about some principles we may want to follow, things we want to think about with regard to how we set up the standards and certification processes.

So, I'd like to first go over some of the key milestones and the timeline just to sort of get a sense for that. Very high level, but we can drill down as people have questions and the like. And then think a little bit about some of the principles that we may want to apply as we talk about standards and certification criteria. Then look at some of the core themes, and then hopefully open it up for discussion to see what is it that is missing from our list, what are the things that we need to take off the list. And hopefully get your input, feedback, recommendations about where we're going with this.

So, we've gone over this I think before, but I think just to sort of reiterate where we're going, it takes us a couple of months to sort of draft the NPRM. And so it typically is going to take us—what would you say, Jodi? Maybe three months or so put together and to go through clearance and to sort of—

Jodi Daniel – ONC – Director Office of Policy & Research
Easy for you to say.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
What was that?

Jodi Daniel – ONC – Director Office of Policy & Research
Easy for you to say.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes. Three weeks? Was that—I think for the record, was it three weeks?

And so what that means is that if we'd like to get something out before the end of the year and give people an opportunity to begin looking towards and building towards meaningful use stage two, really the fall is when a lot of this stuff is going to come together for the kinds of things that we need to recommend and to put into the NPRM. We will have some time after that to get feedback about the recommendations that are put into the NPRM, and the suggested standards and certification criteria. It also gives us some time if there are tools and infrastructure or tests that need to be developed, we can begin working on those as well. But we really are trying to get as much of this out there as quickly as possible so that we can—the industry and others, can start building to that and be successful in the next stage of meaningful use.

So the office of no Christmas will become the office of no summer—I think that's probably correct in the sense that we have a tremendous amount of work that needs to be done in preparation for stage two. And I think the work that we have involves not only preparation for meaningful use stage two, but also to look back at what happened and what worked and what didn't with stage one, and make sure that we refine that as we go into stage two and can make some improvements if necessary.

So the key timeline constraints, the NPRM must be drafted and undergo this regulatory clearance well before the publication, and then before we do the final rule we have to have comments and analysis of the comments and sort of their drafting and regulatory clearance. Once that happens, and one would hope that the clearer we can be in the NPRM the sooner we can develop the certification testing scripts and infrastructure. Those things all have to be developed, vetted, and implemented. And all of this has to happen in sufficient advance lead time so that EHRs and the EHR modules can do the software development certification and upgrade and testing as necessary.

So we've got an ambitious set of tasks that need to be done. I think one of the ways that we can try to think about the work that we have to do is to think about some of the principles that we need to examine. So the best way to predict the future is to invent it, which means if we want to try to get to the point of certification and testing, the more we know going in, we can sort of help us get there.

The future is already here. The problem, of course, is that it's not very evenly distributed. And so part of the stage two meaningful use is to start to distribute the future a little bit more evenly as we begin to move people forward. And Calvin and Hobbes, of course, those great philosophers that we all know, the problem with the future is it keeps turning into the present. And we feel that acutely as we go into stage two meaningful use is that it seems like it's in the future, but actually it's pretty much the present. And so we really have to think about how we're going to help advance stage two meaningful use and do it in a way that allows us time to get the work done.

So, the key principles for standards and certification criteria, we do this because we want to help people achieve meaningful use. And the goals there, as far as ... has articulated, to improve care, improve health, decrease costs, establish confidence and trust so that the public can feel as if we are good stewards of their information and we use that to the benefit of our patients. We want to empower individuals so they have access to their information and can use it to help improve their health. And that we learn from this as we go along so that as we learn about what works and what doesn't, we can feed that back into the system and make improvements.

And I think one of the things that we always need to recognize is that the standards and certification criteria should be low regret. They shouldn't create barriers to future enhancements, and they should be highly leveraged, which means we need to fix those things that are high value, and that advance us as far down the road as we can, but do so in a way that provides at least some options in the future if we need to make course corrections or other things.

So, some of the themes to think about. We need to think about vocabularies and terminologies. And I think about this as sort of an inverted pyramid, if you will, in the sense that we need to be very, very explicit about those things that are healthcare specific, because, quite frankly, no one else is going to do that for us. We may be able to beg, borrow, and steal the way in which security is handled and use the best out there in the industry, but when it comes to those things that are specific to healthcare, we're the ones that are going to have to really do that hard work.

And so when it comes to vocabularies and terminologies, which really represent the essence of what is healthcare specific, we need to have a pragmatic approach. One of the things that John mentioned earlier is that any time that we put an "or" into the regulation, for a vendor that means, "and". And so if we say, "Oh, we want to make it easy, right? We want to let people have options" sometimes we actually introduce complexity by having multiple ways of doing the same thing. So we need to really begin to reduce alternatives in vocabularies and start to drive down towards those vocabularies and terminologies that are going to be useful going forward.

Now, we also need to be pragmatic when it comes to the kinds of things that we want people to exchange. Now, SNOMED, for example, is designed to cover the entire spectrum of everything in healthcare. But if we look at the kinds of things in ambulatory or in hospital settings, we can probably identify a subset of that full vocabulary that we say from an 80/20 or a 95/5, we can probably identify a CORE subset that makes our challenge scalable.

And we need to make sure that we include vocabularies that will help us get our work done around laboratory reporting, care transitions, public health, quality measures, all of those things. We need to really identify what those vocabularies are, reduce the optionality that is there, identify the high value code subsets that account for a significant portion of the volume and the value. And make sure that it covers the range of things that we think are going to be important as we go into stage two meaningful use.

As we think about upgrading from paper to electronic data transmission, again we need to reduce alternatives and try to increase specificity. Increasing specificity, again, if we have lots of flexibility in how we represent our standards, it may seem as if that's a helpful thing. But as we try to get more robust interoperability we need to be able to be explicit about what people can expect to receive and what they're expected to send. And having lots of alternatives also makes it more of not an "or" but an "and." So we need to think about that.

This has to be related to health information exchange, and how we move information around. We should really think about things as being modular, composable. I think that the value chain starts sort of within this committee, if you will. Because if we create complex standards and certification criteria, it's hard for people to implement, it's hard for people to test. It just creates complexity all the way down. And so we need to be very, very clear about how we're going to increase the specificity and reduce alternatives so that we can maintain this as we go forward.

I think laboratory, individual engagement; engaging the patient and public health are going to be important parts of upgrading from paper to electronic transmissions. And we really need to focus, I think, in large part around some of the standards for care transmissions. This particular group, back a couple of months ago, gave us the charge to start working on some of these things, and so we do have some initiatives that have started already. They certainly haven't completed at this point, but looking at many of these things; laboratory, transitions of care, and some of the quality measure work.

I think we do need to think when we think about the stage two meaningful use criteria, there are some that are going to be related directly to meaningful use, but some of the standards and certification criteria we really have to think about as a down payment for things that might be coming in the future. So maybe what we need to do, as well, is to think about how can we get people prepared in stage two for what may become the meaningful use criteria that come in stage three. And so we need to get, for some of the hard problems, get people thinking ahead to what that looks like.

And I think finally we need to make sure that we update the Nationwide Health Information Network specifications so that we've got modular and testable content and transport standards, as well. And that includes Direct, as well as some of the work that's going on right now within the Nationwide Health Information specifications, as well.

So, vocabulary. And stop me, and interrupt if you've got questions. I think one of the things that we need to think about is that if you take a look at what we have in the CCR and the CCD, I think problem lists, medications, and medication reactions and allergies, and results—laboratory results—are going to be some of the pragmatic laboratory subsets that we need to start with. There may be others, but I think this is clearly on the list.

The kinds of things that I think will get us to success is that we need to converge to a single vocabulary for a particular purpose. And what I mean by that is that I don't expect us to have a single vocabulary that handles absolutely everything that we'd want to exchange. But, administrative transactions may need a vocabulary, and those that are around laboratories may need another. Some of the quality measures may need to have draw upon those to help describe their quality measures. I think medications, again, we need to begin converging towards singular vocabularies. And I think the feedback from the industry, and from this committee, can be very, very helpful as we think about that.

I think we need to focus in large part on the ambulatory domain and to make sure we've got good quality reporting and public health. Those are things that we can't lose sight of because we want to make sure that we have vocabularies and terminologies that will support those things. We've also talked a lot, before, about focusing on interoperability, and not on internal representation.

So we need to make sure that when we're doing testing and certification criteria, and we're talking about communicating between public health agencies and EHRs, or between different EHR systems, that we need to focus on what goes between those organizations, not how organizations internally may represent the information and the data. And I think, again, focusing on 95% of the most commonly used elements

and certifying on that 95% subset I think is helpful, because it gives people a target, it doesn't become quite so overwhelming.

I mean, we have to recognize there's a lot of work that's going on with ICD-9 transitions to ICD-10 in addition to the work that's going on with meaningful use. And the more we can help to constrain the problem and make it manageable, that sort of iterative and incremental approach to standardization, I think, is going to be helpful. And as we begin to identify those things, then what we can do working in collaboration with NIST is to help identify tools that will help make it easier for people to get there. We want to certify on the ability to consume data, where the EHR does not understand the code, so that we want to be able to make sure that the EHR can kind of consume that information and we don't have to get into the inner workings of the EHR.

Now, one of the things that we may want to contemplate is that we can—as part of the NPRM—name a standard for a particular purpose, you know, create a singular vocabulary. But then give us some time to be able to identify the subsets that we might have for testing, do some work with all of that in association with NIST, and then use that as a way of making sure that we've got a credible approach to testing that subset for those vocabularies.

So in large part, this is sort of a pragmatic approach. Let's try to constrain our problems, identify what those singular vocabularies for particular purposes might be, and then further constrain that by saying there are certain kinds of subsets that we think are more important, and that we want to make sure that people can communicate across the wire—not internally, but across the wire, around those subsets.

Do people have questions about that? Lots of questions. Okay. David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, David McCallie with Cerner. I appreciate the desire to identify these 95% subsets, because the vocabularies in their native state are so cumbersomely large, but I wonder, practically, what you can do other than facilitate usability and user interface. So, for example, I was working with the SNOMED CORE subset recently, just some development work, and as I think most of you know, it's a 6,000 or so SNOMED terms that were identified by analysis of a number of hospitals actual use of SNOMED and problem lists. And it's a very helpful way to take 300,000 elements and reduce it down to 6,000 or something.

But I quickly found that there were a number of rare but important real world conditions that aren't in CORE. If you watched *House*, essentially every one of his diagnoses ..., but you don't even have to go that far. I think Wilson's disease is not in CORE, and you know, it's rare, but important in real world disease.

So, what does it mean to settle on a 95% subset in terms of the long tail that's not in that subset, but that must, in fact, be managed in real care settings? I don't know how you—what does it mean to set up that 95% subset?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Well, I think that's part of what I hope this committee will be able to talk about and to discuss. I think it's absolutely true that even if you were to take subspecialists, or others, that 95% is going to be different. And the reason there are 300,000 codes in SNOMED is because everybody's subset is slightly different. And if you add them all together, you get 300,000 codes. I think what we have to figure out is how can we—maybe it's not 95, but 80/20?

It's a sort of—we need to figure out what we think is going to get us a little bit further down the road and help make this a manageable problem, while at the same time making sure that there's a way to transmit a code that isn't in that group. It may mean that you, for example, assure that people can do the 6,000 or 1,000, or 2,000, or whatever the number might be, that they could transmit more than that if need be. But if somebody's got an internal representation that is not standardized and they are struggling to try to figure out how they can get to meaningful use, having a constrained set that allows them the ability to get on that escalator and do it in the timeframes that we have, I think is one of those things that we're going to have to try to figure out and balance within this particular group.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Just a comment back on that. I think that our experience, we are constantly challenged with the usability issues of navigating these large vocabularies for look up purposes. A clinician who wants to build a problem list, if you just give them a straight open search of every SNOMED code, it's a formidable, frustrating process.

So identifying subsets that say, the odds are you're going to find it in this short list, and I'm not going to show you these other choices makes sense from a usability view, but you can't—I guess to my—I would urge you not to exclude the ability to add those less common choices, even if it means dropping into an alternate user interface. So we just have to be careful what that 95% means. It's really a user facing convenience, not a system constraint.

M
So actually—and thanks for that—it's actually, that's the reason we're focusing on interoperability, not in term representation. We don't want to constrain anybody's ability to have clinically specific vocabularies for internal representation for workflow for using .... the 300,000 SMOMED codes. But, when it comes time for interoperability, when it comes time to expressing that problem list in a CCR or CCD, that we test on a constrained subset and that we test on the ability to accept a code that isn't in that constrained subset, so when there are rare diseases that come across, we're not compromising the ability to exchange that information. It just might not get exchanged in common formats if both sides don't understand the same subsets.

John Halamka – Harvard Medical School – Chief Information Officer
Yes, so the subsetting is not the creation of a new vocabulary, it's just the creation of a convenient testable interoperability.

M
It's an important distinction.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We've got Jim, Wes, Nancy, and then Chris.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Well, most of the dialogue that was going on in my head was just had, thank you.

M
I got it out before Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Hey, I can't control what the chair does.

M
But we're working on it.

M
Are you going to introduce a new reference for standard vocabulary like *House*?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
No, I always enjoy when someone mentions *House* and there are physicians in the room, because half of them smile, and the other half go .... The point I just wanted to let—first of all, I just wanted to sort of support this notion with the experience with LOINC, where even there's a sort of a difference in specificity of how a lab result is described depending on whether you're someone who really needs to know the method and so forth, or whether you're just used to dealing with lab results categorically. It's a shame to lose information in getting to the smaller code set, but what I understand is that even where people have been forced to implement to the higher level of LOINC, they tend to screw it up.

So a significant layer of that, so as we muddle on this issue, I would encourage us to consider how to do this in a way that doesn't reduce the fidelity of the transmission. That is, if you've got this situation where someone who wants to describe a reagent, or a disease, or a method with more precision than the receiver wants to receive it, that there's a way to handle that. I don't know that it's possible. It may be possible in LOINC, but not generally possible, and so forth, but it's certainly worth something to look at.

John Halamka – Harvard Medical School – Chief Information Officer
Jim?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
A couple of thoughts. One is about care transitions. Obviously critically important construct. I think by care transitions we mean transitions between care processes that are currently isolated. I think that's important, because as we—it is already the case that there's starting to be community-wide shared care processes. Shared among non-co-owned competitive healthcare organizations. And I think it's likely that the critical transitions within those integrated, community-wide processes will have different characteristics and pose different problems than what we're currently focusing on appropriately, which is the transitions between currently isolated care processes.

So now if you go from a nursing home to a hospital to an ED to a primary care, all of those care processes may be pretty much isolated. And the transition is knowing how to switch between those processes. If you really do, and it is happening, it is the case now that if you have a process that actually has been agreed on by all of those entities, and is shared among them, I think where the transition tricks will be may be different—and I think we at least need to have that in the back of our heads and be thinking about what that might look like so that we don't, when we achieve our goal within a few years and really have a lot of community-wide shared care processes, we don't find that we boxed ourselves into some kind of corner.

The second is about vocabularies, and it's related to that. Granting the wisdom of the way you're approaching this, it is the case for those of us who want to run high quality, high efficiency, community-wide, evidence-based, patient centered care processes that, I think, at least, that we will need to use the same vocabularies internally as we use externally. We cannot afford to spend the rest of creation translating.

And also, if we don't have vocabularies that are usable—maybe not required, certainly not required internally, but that are not usable to manage the care processes internally, we also will have no way of communicating with each other, and having a learning community where we can say, "You know, we ran this process like this, and we found that this didn't work." It will be back to the same situation where we won't be able to translate that into anything anybody else will understand.

So, agreeing that the critical thing is that we can communicate externally. The vocabularies still need to be designed at least as much as possible so that they are relevant to internal process management. And so that those two things—internal process management and reporting—become more and more part of a spectrum rather than, again, two completely isolated things that require a whole core of translators.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Well, and I think—and thank you for that. I think that's tremendous. I think one of the things that we can do that may help enable that is if we can reduce some of the uncertainty about, well what should the vocabulary be? If we maintain a series of options, I think people even internally aren't going to necessarily make the investments to align.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I agree with the constraint, totally.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
And so I think that may be the way that we can drive towards that future.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. It's a very important interchange. It takes us back through a thread that's been permeating many of our discussions about the interchange between entities and internal. And you're right, that when one thinks about anybody here that's in a provider environment, you think about the legacy architecture and the conventions you have you'd have to surmount. On the other hand, anything forward, you think about the opportunity where their consistency and vocabulary for interoperability and that really expansion and learning and aggregation. But then it sounds like there may be a sort of evolution that is implied by that, but it's an important component in terms of being sensitive to the capacity to be pragmatic, but also for the innovation to learn.

John Halamka – Harvard Medical School – Chief Information Officer
And so I would concur, this notion you just said about evolution. So yesterday I received this email, "Who do I contact at CMS with complex technical questions? Is there just an email address of an oracle on the other end that will just do everything for me?" And I said, "Well, tell you what? Why don't you try it out on me, I'll be happy to try."

They said, "Do we need to have LOINC codes embedded in all of our laboratory displays that physicians use internal to our organization?" And the answer is, "Well, at least my understanding of the intent is that when we interoperate, we should ensure that LOINC codes accompany our laboratory results, but it is not required that an internal system necessarily show a LOINC code representation to the clinician, or have it as part of ordering."

Or similarly, "Is RxNorm required to be inside the internal system as a way to represent a medication during the order process?" "Again, my understanding is it does not, that you have 11 different vocabularies that are subsumed under RxNorm, some are proprietary, some are not. Feel free to use whatever you want; as long as that medication goes out the door and it's interoperable, it has a vocabulary associated with it that is inside the RxNorm subset."

So hence, I think it's right that we want to stop doing mapping for the next 20 years of proprietary vocabulary to the standardized vocabularies, it's just going to take us a bit to get there. So saying, for now, here is a vocabulary and code set that you can download for free from the U.S. government Website that's the source of all truth, for 95% of the conditions and the meds and the labs, would significantly ease the burden and eventually get to the nirvana of using an internal sources.

M
So in the spirit of the big society that takes this concept from across the pond, I'd like to propose that all standards committee members serve as Help Desk....

M
... I mean, I agree with you, the case for this constraint set that's used for interoperability is spectacular, but for instance in our health information exchange, where we are using LOINC as one of the methods besides just printing—having electronic documents for sharing lab results, we are back translating our internal display of lab results so that they will be consistent with the health information exchanges display of lab results so that users that use the exchange will only have to get used to one interface. Now we're not distorting the internal, but we are changing it, particularly where there are just nits and the internal. So, all I'm asking is just to make sure that to the extent that it's feasible, we keep extensibility in the back of our minds so that we can make that incremental movement from here to somewhere.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great, ... Let's go to Nancy Orvis, and then Chris Ross, Stan Huff, and then David McCallie.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Doug, good talk. I wanted to put a context in the fact that I work for a very large institution where I deal with interoperability for 62 clinical specialties, and actually did some work in the last five to seven years where we looked at what were the top 75% information exchanges between our applications? And my goal back in 2004 was to make sure we named a data standard in every one of those key—if those were the top 75%, we wanted to make sure that there was standard data in there as much as possible. And that was very useful, because you can look at—okay, administrative transactions have been pretty well taken care of by the HIPPA transactions.

And if you start looking at volume of issues, checking enrollment eligibility is huge. Is this person eligible for care in my institution? Yes/No. What's their ID? Who's going to pay? What's their doctor? Where are they enrolled?

The next thing was just-- And I think the 75/25 is a very good way to go down the road. It's also the issue of manageable chunks. So I have 62 clinical specialties. My internal systems allow them to do templates on their outpatients so that they can put their top 25 problem list in their own internal system; if it's a pediatrician they are doing otitis media and shots and well baby visits, if it's an oncologist he has a different set of top 25. That doesn't mean that has to be in the Institutional Exchange between the organizations. And I think that's critical; what is the institution's volume of exchanges, what kind of consults does it send out, what kind of consults does it get back in.

It takes some internal analysis to understand what does your provider organization do, and I think you could look at helping--we could probably put some examples out to help to do that. I've often thought that the lessons learned we did with Federal health architecture would help all the regional HIEs. It's very much what is most important in your state or region to exchange; what's the top priority, let's focus on those, let's save the other stuff for later.

And my other point that I wanted to make about it is I enjoy working for a really large institution, but my own set of family doctors is five or six, and it's fun to look at the difference between the mega institution and my one internal medicine doctor who says he's a single practitioner with one front desk person in a building with 56 other doctors. He's saying oh my how are we ever going to do this, do I want to do this, and he's still getting faxes for the lab results.

And my thought on so let's talk about let's make sure we have-- I certainly would like to see the top 300 orderable lab tests and results be in a standard vocabulary subset. You do not need to exchange 20,000 lab results. However, and the point would be, if it ain't on the list fax it. I mean even the family practitioner says if I don't need that, if I'm looking for just what happened to this patient in the last 30 days, but there's six months of lab data, I'll ask for it, but I don't want to get it on the first time I ask about this patient.

So I was a little bit of the KISS principle in some scenarios saying yes, you might not have an ability to exchange this new rare disease. You're going to call that receiving doctor that you're sending a consult to or you're going to fax a copy or make a PDF copy and say here carry it with you. And I think that's the pragmatic way. I would say that we're going to just have to deal with that. I do not expect that the DOD will have many trading partners right now that we'll be able to send all 20,000 LOINC codes if there happens to be that test. However, I would expect that at commercial labs that I'm doing work with, and in fact I would like to see that. That's a different issue.

But I think one thing I also wanted to mention about yes, systems will eventually, or you might be looking at vendors could look at the opportunities, to start putting native reference terminologies in there and say what the business model could be. I can help you interchange with anybody in the world; I'm not selling you-- It would be nice to see that; that I can do this for you, and I'll give you this really important subset of data so that you can manage 62 clinical specialties, but if you need to exchange outside I can do that for you, and I can do that better than vendor B, C, or D. That's my second point we'd like to look at.

And the one other thing is your mention of RxNORM is really important. About eight years ago we had the British come and talk to the Vocabulary Committee where I was at HL7, and talked about having a uniform syntax to display a patient medication list. And I've often thought when we looked at RxNORM why could we not be saying that that's the syntax, capital letters and small letters, the syntax of where orderable drug, dose form, root of administration, became the default norm so that any time you sent a patient medication list it was in the same syntax. Patients would get used to seeing it the same way, they would not be confused by having milligrams before frequency, that kind of thing.

And although Betsy Humphries has not said that was the original intent of RxNORM, I think part of this issue of HIE Exchange is that part of it, and consumer education that came up in yesterday's talk, is how much computability is the consumer going to be able to take. We should be looking at something like that with RxNORM, or whatever, that patient medications come out, that the issue of although your system may not currently have RxNORM embedded in it that you start looking at ways to just translate to a common internal syntax so that it looks, sees, and feels the same across the United States. That's all.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Nancy. We heard the call for pragmatism in your comments, and I know this is one of the things that we'll consume, really the thoughtfulness of the go-forward work and the balance between pragmatism. I want to make sure, Wes also had a point earlier, is that there is a loss of nuance when one goes to smaller stuff; it's the lumper/splitters for the clinicians. And we're going to be living some of that with the implementation of ICD-10 in terms of the value and sensitivity for nuance provides versus a practicality of a smaller set, and that may give us some insight or an analogy to contemplate as we push forward with this work.

Let's go around with the group that we had up; we had Cris Ross, Stan Huff, David McCallie, Wes Rishel, and then Jamie, and we'll take that to Doug for the next set of comments and the next discussion. Cris.

Cris Ross – SureScripts
Thank you, Jon. Cris Ross with SureScripts. I think you're doing exactly the right stuff. I just want to ask a question in detail, on the last bullet point under Constraint for Success where you talk about certify and ability to consume data where the EHR doesn't understand the code. In the spirit of conversation and comments here I'm wondering if you've thought about, and what your recommendations might be, around consistent processes for exception management and error handling, to not simply say that you can handle an exception and do something with it, but to either recommend or require that when an exception

occurs that you may or must handle it in a particular way. That might get to things like loss of fidelity that Wes talked about and some of the other examples that Jim talked about as well.

M
And one of the things that we have to be vigilant about is sort of the robustness principle from Postale, which says when you send you should send conservatively, which means let's make sure that we test people, that they can conform to the standards when they send. But when you receive you should receive liberally, which means you need to be able to sort of say if somebody sends me a code and it's not on that list I have a robust way of managing that and that the system doesn't fall apart as a result of that.

So I think your comment is absolutely kind of the right direction that we need to go. We need to make sure that we test so that people conform to the standards so that when we send something we try to make sure that people send it in the right form. But if somebody messes up or they got the code wrong or it's not a code that's on the list of the ones that you accept we have to have a robust way of trying to do our best to figure out what that was and at least acknowledging that you sent me a code and I'm not sure I know what it is. Or maybe we need to make sure that there's an accompanying free text version of that that we make sure that we have if we can't read the code at least we can read it in a human, readable form what's there. But I think you're absolutely right; that, I think, is going to be the way we can both manage the problems and the challenges in the short-term, but create a path forward so that we can enable interoperability and gradually expand what people can read and what they can manage.

M
I'm sorry, one addition to that. I don't think it's in anybody's interest to constrain particular business processes, and there may be EHRs that do it in a particularly elegant way. There may be some core areas that are patient safety related, so for example interaction checking where the medication allergy or the medication is uncoded is a classic example. There are clear regulations for display of medication or lab information, even in areas where the lab itself is uncoded, so there may be areas where there are patient safety issues that need to be addressed. I guess that's the distinction that I would make.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes. Thanks. Stan.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So comments in two areas. One quick. So I'm sort of testifying on my own behalf here. The LOINC Committee is certainly open to enhancement. We're doing a lot of work right now looking at the way people make errors in mapping the LOINC codes and when there's loss of fidelity between the local code and the LOINC code, and so that's an active area of concern. And it's not a deficiency of LOINC, it's actually the complexity of doing it right, of matching reality to an arbitrary framework of any kind, but I think that's solvable. We're looking at classes of errors that with some further guidance from the LOINC Committee I think could improve that accuracy. So that's a brief comment.

Then the other one is just a reminder that determining terminologies is insufficient for some of the kinds of data that we're talking about. So with laboratory data 99% of it can be sent fine with just a single LOINC code or some other observable code as the code. It's just a reminder that the value sets we're talking about have to be actually very much connected to a specific information model that gives you the context of use of those value sets, and without the model you lose interoperability. The models often are provided by HL7, and so you get a dose or a route or a medication code field in the standard that's been adopted, but for a whole series of common kinds of clinical data you need to go beyond what's been accepted as the standard. And so the kinds of things if you just start talking about heart rate, problem with blood pressures, skin assessments, which should peak a lot of the folks at the VA and the DOD and others who have been working on skin assessments, you have to go far beyond the simple Exchange model that's in HL7 to get to interoperability.

And so at some point we're going to have to have a discussion about CDA templates and implementation guides and detailed clinical models and those aspects of this Exchange, because the details of how you

pre and post coordinate the concepts are not specified by the standards currently. And that's not to say we can't do a lot; with the 80/20 we can probably do 80% of it and ignore that, but when we want to get to the 20% then we're going to have to tackle some more sophistication in the information modeling aspects of this.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Just as a quick comment. In the transition of care work that we're doing in the S&I Framework that's exactly the model that we have, which is to say there's a core set of information that needs to get transitioned on every kind of transition of care, but/and there are specific domains where you want to go above and beyond that. And so the approach that we have should be to ensure that there's broad interoperability, but not constraining the ability of people in particular care settings, particular care areas, to go above and beyond that with specific clinical information models and vocabularies for dermatology or for cardiology or neurology or for what have you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, it may be a redundant comment due to the cascading comments that are preceding, but just to come back again to the notion of subsets. The goal should be to eliminate gratuitous optionality, but not to try to restrict specificity. So there's a lot we can do to simplify without constraining specificity. You need to be specific in medicine, and it's going to get more so, obviously, as we begin genomic medicine.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Wes Rishel, I think you're up next.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you. I just want to sort of recite a bunch of things we've said and comment on them.

I think that fundamentally we've known for several years now that in the field, that is across organizational boundaries, and the percentages vary according to whose study it was, but something like 95% of the data can be described with 800 LOINC codes. I'm sorry, all of the data for 95% of the patients can be described with 800 LOINC codes and 95% of the data for the other 5% of the patients can be described with those same small, and getting to making that the nucleus that everybody implements is a critical goal for us to accomplish in stage two.

I think that as we go forward that will mean we have certification testing for EHRs that can receive a code they don't understand and continue to make, pardon the expression, meaningful use of the lab result. That is to say it's not sufficient to say oh we're going to alert the operator that a code came in we didn't understand. The certification requirement is that if twelve results come in, if a set of results come in and you understand nine of them coded value then you can trend those, you can alert on those. For the others you can still display them on the screen, and then the requirement is to certify that for this nucleus of codes; they're treated as data rather than unknowns.

I think that this issue that Stan raised, that I keep calling information molecules, represents an important opportunity to lay the groundwork in stage two for more use of the notion in stage three. That is to say if in stage two we have thought through, and by thought through I mean in the next couple months we thought through how to plug in those descriptions, maybe we have one that we're required to certify or something like that, then we have the basis for adding more descriptions in stage three, just as we have the basis for adding more codes to the nucleus set of codes in stage three, because once everybody has the process down making a couple hundred more codes standard is not bad.

And finally, getting back to Jim's earlier comments, we have always, I think, had a distinction between internal transmission of data, which is not our problem, and external transmission of data, which is our problem. Jim has raised the point that it's not quite as black and white as that anymore; there are closely allied external organizations and what can you expect of just any arbitrary EHR you deal with. I think we

have to deal with that by following the path that we're currently following, which is that we certify for the way you interoperate and we establish meaningful use on the fact that you have interoperated, whether or not you use the certified way. And I think that it's important that we not try to even envision or close down the opportunities for relationships among what Jim likes to call accountable care communities, as opposed to accountable care organizations, based on the expectations with an arbitrary doctor's office somewhere that you're not really working with day-to-day.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Pretty nice synthesis. Appreciate it. And I think then you know really this thread through many … much discussion and much to work on in that.

Jamie, let's comment then we'll turn it back to Doug to take through the—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. I'll try to be brief. So I guess, first of all, Doug, I wanted to thank you and commend the direction here. I think that this is both very good and really in keeping with the previous work of the Committee, so I both wanted to put it in that historical context of the work of this Committee and also think about some of the next steps in this direction for the Committee.

It's very interesting for me to look back on the set of original work products from the first year of this Committee's existence where we actually were recommending a single vocabulary for each of these three things. So we had recommendations for SNOMED CT for problems, LOINC and UCUM for results, and RxNORM for medications, and so I mean I'd love to go back and dust that off and come back and have those discussions again and see if anything has changed on those.

But I also think then that in terms of the recommendations of the Vocabulary Task Force from last year are completely aligned with the direction on the subsets. And so just reflecting on this overall direction it does seem to me that that lion's share of the work really is going to be on focusing on the subsets, the picking of the subset; is it the 75%, the 80%, the 95%, how is that determined. But also, perhaps more importantly, how are those subsets supported and made easy for the implementers of the EHRs. It's not just how do you pick it and how do you maintain it and how does the constraint and the governance process for the subset work, but also what's the infrastructure that's made available to make it easy for implementers to use. And that's something that really we have not focused on so much, but that might potentially be some work for this Committee, I think.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well said. It is real in the implementation, so that definitely is a charge.

There have been a number of suggestions for framing the subset based on traditional experience, as well, I imagine, the academic literature. And I think since we've offered this up and put it on the table, if there are any references to document that I think that would be helpful, and recommend that we get those to Judy for the Committee and the public, and for Doug and Arien for their contemplation and follow-up to the discussion. So I appreciate that.

And Doug will go through the last stretch of—

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Well I just want to appreciate the discussion here; I think it's been tremendously helpful, and I think it's provided a lot of context that it is not an accident that it is consistent, and so I think that is something that I think is important to recognize.

Now I have three other slides, and I think a lot of the discussion that we've had here can apply to some of those other slides. But I just want to sort of rapidly go through those just to give you a sense of some of the other work that I think we need to look at for meaningful use stage two.

So in addition to vocabulary and value sets, we need to think through what are the other pieces of the puzzle that we need to bring together that will enable interoperability as we move from sort of paper-based ways of exchanging information to ones that are electronic. So we'll have a little bit more time to talk about Direct in the next hour, but clearly some of the things that we need to think about in terms of additional pieces of the puzzle around Directed Exchange is we have to have transport, and we have that in some of the specifications that we have for the Direct Project, but in addition we need to have certificates, and we need to have certificates that are interoperable. There's a lot of information that can be placed in a certificate, and we have to make sure that we have the right bits of information there so that certificates can be used across many different exchange and exchange partners.

I think we also need to think about directories, and we've received some good advice from the HIT Standards and Policy Committees about both individual level directories, as well as organization level directories. And so all of those pieces together provide a necessary tool that you need to be able to do Directed Exchange.

When it comes to laboratory results we have do have a Standards & Interoperability initiative to look at how we can reduce the complexity and converge on a constrained set of specifications that is inclusive of the kinds of things that we might anticipate for meaningful use. So not a specification that handles everything and not one that's tightly constrained for a specific use case, but something that is adjustable when constrained and easy to implement, and that's work that's ongoing.

We also need to have the vocabularies that are associated with that as well, and I think this 80/20 or 75/25 or 95/5 is a rule that we need to apply to that as well.

And finally, for public health here, we have electronic lab reporting, we have some of the work around reportable conditions, and again we're going to have to refine the implementation guides and the vocabulary subsets that can help address some of the public health reporting that's required.

For transitions of care Arien sort of described parts of that particular project as well. This includes things like Directed Exchange between different care providers. It means an area where we can bring all the pieces together in some sense around medications, medication reactions, allergies, problem lists, and laboratory results. We need to make sure that for different kinds of transitions of care there are common content sections, as well as transition specific content sections. So there may be a core set that everybody needs to be able to exchange, and that perhaps for moving from a hospital into a long-term care setting there may be some transition specific content that might be necessary as well.

And I think throughout this, as we think about the things that were adopted within stage one meaningful use, we need to learn from that experience, and we need to make sure that we refine and update existing content standards to reflect the knowledge that we have as we try to get not just to having electronic specifications, but electronic specifications that are constrained sufficiently that we can promote interoperability. And we need to make sure that we include the individual when we talk about transitions of care so that the individual is one of the participants in that exchange, and what does that look like using patient-centered healthcare records as one of those transitions that we might want to support.

When we talk about the down payment to the future I think one of the things that we have to address is things like the PCAST report and what does that mean when we have a refined set of metadata standards that would support that in a universal exchange language. We also need to think about some of the more complex exchange patterns that are out there, like the query retrieve model that's currently within the Nationwide Health Information Network. And so we need to explore what we're targeting as low regret standards for future information exchange that will support innovation, that will support a learning healthcare system, and that won't box us into a corner that will make it difficult for us to get to new ways of doing exchange, and perhaps ways we haven't at this point even thought about.

So there are a couple of different candidates. These are certainly things that I think we may not have time to discuss today but I think are things we need to think about over the course of the summer and coming into the fall. So things like synchronous secure transport. So we have ways of doing that using

Service-Oriented Architectures and Web Services Security. We could also do this in a more RESTful way using HTTPS and some OS II and TLS methods. We've had a lot of discussion with security and the privacy work that has gone on out of this Committee, and we need to leverage that as we think about not just asynchronous transport, which might be a Directed way of doing things, but those use cases in which we really need to have a synchronous way of exchanging that kind of information.

I suspect that there's a subset of the current specifications for exchange that might fit along that low regret path, and we need to identify that. We need to kind of create that modularity, and we need to make sure that we can test that effectively as we go into the next stage of meaningful use.

Metadata for a universal exchange language, that's described in the PCAST report, perhaps we can find from existing exchange standards a subset that would serve the purposes of that starter set for metadata exchange. And if we had a small constrained set of metadata that we say this is the group of metadata from existing exchange standards that helps us with data providence, that helps us with granular consent, or that helps us with patient matching and identifying that data, if we can get that small subset, it may not be everything and it may not be all the things that we need, but it's something that's on that low regret path that tees up in stage two meaningful use potentially new ways of doing exchange for stage three meaningful use.

And I think we also need to think, too, about distributed queries that support risk adjustment, quality reporting in public health. Without standards there's a centralizing tendency, because it says just send me what you have, I'll take a look at it, and I'll try to figure out what it is and do my quality analysis and reporting and things like that. I think the more we can create standards for how we do that quality reporting and public health reporting the easier it is for us to distribute those queries and say I want to understand something about the pulse of the nation with regard to how to we manage diabetes, but rather than centralizing that if we understand clearly the definitions of diabetes, what the appropriate inclusion/exclusion criteria, how we define quality, and the language for how we might issue those queries, we have the opportunity, I think, to provide, again, low regret, different kinds of models that might be out there with regard to distributed query as well. And these are the kinds of things that may not at present map directly to a quality measure or a particular meaningful use criteria, but it's one of those things that I think needs to set the stage for what we anticipate might be coming down the road for meaningful use stage three.

So with that that's my last of the three slides. Certainly I think the discussion that has gone on before this has been very helpful, and I think that many of the comments are also applicable to not just vocabularies and value sets, but that pragmatic approach that we need to take around the content specifications and the path of least regret when it comes to the future information exchange needs so that we can support innovation in that learning healthcare organization.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well thank you, Doug. That's just a terrific tee up of future work and direction. Already a couple of folks that … up to engagement discussion on this last part of the conversation. Let's start with Jamie Ferguson and David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I was up first …

Jonathan Perlin – Hospital Corporation of America – CMO & President
Oh so then David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Okay. So you may not be able to answer these questions, and they are asked in the spirit of tell us what you can, but we talked in the previous slides about reducing optionality. This slides opens lots of new optionality, and I'm particularly thinking of subsets into an exchange, new modalities specifying HTTPS, and RESTful approaches instead of the SOAP standards. And then in the news last week or so was the

creation of an independent foundation to manage the existing CONNECT software, which Alembic, Aurion. What's the message to those of us who are trying to implement HIE? Should we stop and wait for this to get settled or should we proceed with the CONNECT knowing that it might get simplified radically? What are we supposed to do?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
At the end of the Direct Project update we actually have some slides to address just precisely that around CONNECT, and some of the misconceptions that are out there and information so that we can help clarify that as well.

This particular slide in large part has a lot of different candidates listed. Not so much that we would expect there to be significant optionality as we go into stage two meaningful use, but in fact I think that there is still the need and the opportunity to have discussion about what would be the right things to include. What I didn't want to do is present a list of here is what we should include when it comes to query retrieve and PCAST and things like that; I think we still are waiting for the PCAST Working Group to provide some recommendations.

But I will say this to sort of the point about what we should do, I think when I take a look at the Nationwide Health Information specifications the way the current on boarding works is that you have to certify to the whole suite of possible kinds of exchange to be able to come on to the Nationwide Health Information Network. It could be that you only want to do one or two of those functions, and so we need to be able to provide people the opportunity to meet all of the security requirements and to make sure that we assure that part of exchange, but to able to say, in some sense kind of like we do with modular certification, is that I only want to be certified for these kinds of exchanges, I may only want to do synchronous secure transport, maybe I only want to use sort of a Direct way of doing things. But I think when we think about defining the specifications in a consistent and reproducible way, and doing it in such a way that we can provide adequate testing, we have to make sure that we provide, again, a modular and extensible way for people to get on board.

I think the HIE needs to continue their work; part of what advances our understanding about what works and what doesn't is for people to go and do those things. But I think when it comes to the responsibility that this committee and that ONC has is that we need to make sure that we can establish the conditions of interoperability, which means we define them in clear and as unambiguous a way as we can with our specifications and the standards, and that we then hold people's feet to the fire and test that they can do that. We won't get there if everybody simply uses the same tool. And so CONNECT is a really important tool and it's a valuable part of that ecosystem, but the strategy isn't that everybody uses exactly the same code base. I think the appropriate role for ONC is to make sure that we establish clear and unambiguous standards, that we provide clear specifications, and that we test that people can follow those particular specifications to ensure interoperability.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Right. And I certainly understand the distinction between a code, a base, and the specifications, but you have specifications, potentially new and I want to say radically different, specifications on the board. I actually personally think they're good choices, but that they are disruptive to the notion that we know what we should go build, because we don't if those are still optional and if these are going to be coming, at least certainly in stage two timeframe.

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Yes. Well these are all things, remember this is part of the down payment part, and I think what we need is we need to make sure that we, again, have the opportunity for discussion. This is not meant to suggest

that in stage two meaningful use this is a list that needs to go on there, and in fact in some sense this is inclusive of lots of things, because I think this is a group that can provide some advice and input into what of the things on that list should be in stage two and what maybe needs to be in stage three.

John Halamka – Harvard Medical School – Chief Information Officer
So just a thought here, David. I think of this as an interesting time in an evolutionary path. So when I was running the HITSP organization, many of you were there, you could never specify architecture. So complete interoperability specifications, but you can't specify architecture. Well that would be like saying we can't specify any of the architecture of the Internet; we can talk about that there's FTP and HTTP and SMTP and DNS servers and certificate authorities, but you guys can figure out it. I know, we'll e-mail search requests to Google and they'll e-mail us a result back, right, because we had to be so neutral.

What will happen, I think, is that standards aren't so much made, they're adopted, and so what's going to happen is we're going to throw out the Direct Project and we're going to toss out SOAP and REST and we're all going to build a number of things and pilot and test a number of things, and I suspect we're going to converge on a fairly constrained set of optionality. It's going to be painful, it's going to take some time, it's going to be incremental, but I really do think we'll get to the point where if it's a point-to-point transaction and you're sending something from point A to point B does it really matter. Use Direct. I mean it works. It's there. Oh, you need to do a query response transaction. I know the REST/SOAP contingent still isn't quite settled, but we'll get to one of those two.

I really do think we just have to move forward with pilots and experiments, and I think we're going to have a variety of HIEs that are going to create value in their local areas, and convergence will come. I wish I could just say it will be SOAP or REST and it will be one of those two, we could just do it and it will be happening tomorrow. I'm not quite sure we can do that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
This is a good point of transition. The next part of the conversation Arian is going to lead, so let's take Cris for the last comments here and then move into what would really follow through nicely from this discussion.

Cris Ross – SureScripts
Well I'll keep it brief. I think 120 years ago there was a raging debate about the merits of alternating and direct current, and it turns out that they still exist today because alternating current is strongly associated with whirring generators and direct current is strong associated with batteries. So when you talk about low regret standards it seems to me as though one of the things that would be most helpful is if we could begin to separate what's alternating current and what's direct current; where does one of these models make more sense than another. Because the place where the debates become frustrating is when we're arguing about is alternating or direct current safer, or other kinds of things, when it has completely other characteristics to it. And I think ONC can be helpful to us in that regard if you can identify synchronous transport versus asynchronous transport or some of the other characteristics you've already put in place.

M
Good good, Chris!

M
that analogy is absolutely perfect, because if folks remember back to that debate it turned out well what will kill a dog versus not kill a dog; direct current is safe, alternating current is horrible, etc. But then people figured out if I need to send electricity over long distances direct current just doesn't work. And so hence this whole point I was trying to get at is that we're going to have to try both AC and DC and then

figure out for the precise use case and an architecture what works best. And yes, if we can do it with as little optionality along the way that would be helpful.

M
You don't want to end up like the traveler who has to carry a bag full of adaptors for different voltages in different countries right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Sure. John, …

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
John … Right now in Japan, this is Wes Rishel, one of the problems they're having getting power to areas is that half of the country is 50 cycle and half of the country is 60 cycle. So there is some benefit to choosing one at that level, I think.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Nancy, very briefly.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Just that analogy is really good from Cris. This is Nancy Orvis. I just wanted another thought might be high bandwidth/low bandwidth. I was reading something about still issues about rural care versus cities that have 4G or 3G or don't, and that's another thought, too, whether being able to send simple messages with attachments is better for rural physicians or not. Something like that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great points. My young colleague here asked us to remember back to the AC/DC debate. I'm sorry; it was before my time I think.

Cris Ross – SureScripts
Yes. Come on, you've seen the movies.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I sure did. Great set of metaphors. The one thing that ONC I think has done so phenomenally is to keep us threading a path that's goal directed; that stage one builds from stage two, the anticipation builds towards stage three. And one of the things I heard in this, or one of the things I take away from low regret, is that as we move forward those who are really trying to meet the goals of meaningful use do not regret having adopt it or finding themselves in a situation with other standards. This needs to be an expansible step that builds on foundational capabilities and expands to future capabilities, and I think that's the challenge. This group has worked with ONC and the Policy Committee wrestling with the speed of adoption, the structure versus the fluidity in terms of really fostering innovation, but a thread that really is sort of cumulative in terms of being clear on directionality. And so I think that's one of the things that's very helpful, and I think also is fundamental for understanding the relationship of Direct to an evolution of exchange capacities that broadens forward from, frankly, more circumscribed use cases to capacity for synchronous and more complex situations.

Now let me turn to John Halamaka to introduce this thread of discussion.

John Halamka – Harvard Medical School – Chief Information Officer
Sure. So as folks know, we want to make sure that this Committee is very much a part of the S&I Framework, and that is that as new ideas about what needs to be standardized are generated at ONC that those are vetted by us, we comment on those, work begins, we are kept updated, and then as work

completes we are given the opportunity to look at the lessons learned along the way and offer comments. And so in this way we provide ourselves, I think, as a great advisory resource to ONC, and we're constantly at touch points with the process.

Well this is a perfect example of such a touch point as we have been watching the Direct Project over the last several months. We said, Arien, come back in March when you have live installations so that we can hear about how in practice it actually worked, and so Arien is here for such a report.

Arien Malec – RelayHealth – VP, Product Management
Thank you very much.

All right, what I'm going to do is give the brief, brief background on Direct; everyone has heard this presentation a thousand times, so I won't spend much time on it. Really make the focus on what's actually going on right now in terms of live implementations, constrained around live implementations in specific implementation geographies that we've been following; there has been some use in the live in the wild outside of that, which is great. And then talk a little bit about the technology providers who are involved in those live implementations, as well as what people have been reporting in terms of findings and experience. Talk a little bit about the ecosystem in terms of announcements that have been made around implementations of Direct Project, both now and in terms of live implementations, as well as plans for future implementations and what that ecosystem is starting to look like. And then we'll transition to a brief update on the Nationwide Health Information Network exchange and, as Doug said, what's going on with the CONNECT Project. So it's a lot of stuff to go over, and I'll try to keep the first part of the material very brief.

So it was actually Liz and Judy, it was the Implementation Workgroup, in October of 2009 that heard from a variety, a panel of providers ranging from the largest commercial IDN in the country down to a solo practitioner. I think one of the striking things that was heard in that session was that the reality for most smaller practices is fax and paper. And even some of the simplest things, like I'm transitioning a patient from my place of practice to somebody else, we both have the same EHR, we both have interoperable representations of the care summary, but I just can't get the document from here to there because there's no way to just push it, that's what we took on in the Direct Project was simple standards to do just that that were simple, secure, scalable, and standards based.

And what we came out with, we found out there are a bunch of different ways of doing it, but what we came out with was a simple specification based on SMTP and S/MIME, SMTP for the transport, S/MIME for the identity and the security, in a mode that allows you to push information, both unstructured and entirely structured information, and allows you to satisfy the common conditions for trusted interoperability for information exchange that's Directed. Primarily, the condition of being able to have confidence that when you send it the receiver is the entity that you intend to send to, that when you receive a transaction you have confidence the sender is the entity that you think you're getting the transaction from, and then, critically, high confidence, guaranteed confidence that nothing that is not under your control happens to that information in transit, and that that information is secure and encrypted between point A and point B.

As I mentioned, the why of Direct is the reality that first of all Directed Exchange is a core part and parcel of information exchange in clinical practice and that the predominant mode of information exchange these days is fax and paper, and that if we can get a secure universal upgrade from fax and paper to electronic exchange in support of the common transitions of care and the common needs for push transaction the country will be in an improved position with respect to providing better care and better health and lower cost for patients.

Very critically we recognize that Direct is a piece in the overall puzzle, that Directed information exchange is one mode of transport that satisfies some key and very important use cases and clinical needs, but it is not, and is not intended to be, the only mode of transport. And then, in fact, query retrieve, other kinds of more robust information exchange capabilities, will occur simultaneously with Directed Exchange. In some cases I intend to push information to you, in some cases I intend to push information to a central place that's available for other people to look at and to pull information with the patient's consent, and then, in fact, in many cases I'll do both, and we'll talk about a case just like that that's currently occurring in trial implementations or in the early implementations. I'm not going to go through all the material here, but just the importance that this is not a hammer for which everything is a nail; this is a specified tool when you need that tool and it's a tool in an overall toolkit, and we really do need a toolkit approach for information exchange, because sometimes you need a hammer and sometimes you need a chisel and sometimes you need a saw.

All right. We have, and actually over time, we started with I think about six implementation geographies. We've seen a flowering of implementation geographies that have occurred during the course of the Direct Project. Just for key background, we started this project a little over a year ago; we launched it March 1st and started out first meetings about mid-March. We got to the first, as everyone heard, we had our first transaction in January, so about nine months from start of project to first production transaction, and now we're in a place where there are a variety of implementation geographies around the country. If you look on this map some of these are live, some of these are about to be live, but we're going to focus in terms of the experience reports on the implementations that are live where we actually have real world experience.

So I'm going to start with the first in country implementation that went live in Minnesota. This was a set of transactions between Hennepin County Medical Center and the Minnesota Department of Health for immunization exchange. What was interesting about this is it was both a-- And I apologize, I think just the immunization specific information has been transmitted forward to Public Health. The intent of this and the way it works is that it supports the same transaction both for Public Health and for transition to individuals, so you can send the same immunization data both to the Public Health Department and to a personally controlled health record that's under the patient's control.

So the Hennepin County Medical Center is a high volume medical center in conjunction with the Adult and Pediatric Trauma Center, and with the other work that's being done in Hennepin County, is sending high volume immunization data to the Minnesota Department of Public Health. This was a Directed mode of exchange that actually involved use of the Direct Project and a coupling, if you will, to FIN MS, which was adopted by the Minnesota Department of Public Health. So this is Direct with a FIN MS adaptor at the end, so it goes from Director to the HIST via Direct and then via FIN MS to the Department of Public Health.

In New York this is sort of an interesting mode where MedAllies took a group of providers and the EHRs who served those providers and put together a mixed mode HIST. By mixed mode meaning they support the common Direct specification, get to people at … specification, and support the use of the XTR based transaction for the EHRs that can plug in. This organization did a lot of the development work on the gateway specification and the gateway implementation in between SOAP and SMTP. And one of the things that we've learned out of this is the value of having an upward path for organizations that can support more sophisticated forms of exchange while preserving a common baseline of exchange for everybody in the community.

Rhode Island the RIQI is the triple threat, the triple play in the country; it's both the HIE grantee, the REC grantee, and the Beacon Community, and they've been early adopters and early components of Direct

focusing on two modalities. First is supporting the existence across the state of Direct to transport and HIST for provider-to-provider transitions of care and supporting Direct for their statewide HIE current care to enable longitudinal management of information. This is critical for them, because they wanted to make sure that across the community they had an ecosystem for Directed information exchange to support transitions of care and that they could use the exact same specifications, with the patient's consent, to push information to current care from longitudinal management in support of their Beacon program, and they've been leaders in this. They recognize that the policy implications for Directed information exchange and support for treatment purposes is very different from the policy implications for pushing information to the HIE for longitudinal care management across different settings of care, and so they've been trying to make sure that there's an ecosystem for doing it all and for supporting advanced forms of information exchange and the most basic forms of information exchange.

Maryland and the District of Columbia is an implementation pilot from an organization called Secure Exchange Solutions that took the Direct specifications and integrated them with a set of PCMH providers focused on more connected care across the community between Maryland and D.C.

And then in Virginia the same kind of model between Dominion Medical Care and MedVirginia focusing on their PCMH implementation. This has actually been a theme; a lot of the early adopters of Direct have been also early adopters of ACO and PCMH, and I think we're seeing a lot of use of Directed Exchange in support of patients that are medical home and in support of higher quality care for care transitions.

And then, last but not least, Missouri, I think actually Missouri was third in production, supported the Lewis and Clark Health Information Exchange and Hartman Health focusing on care transitions from acute care to long-term care, really an upgrade from fax and phone to electronic transition. And Cerner has been both the HIST and the EHR in this transaction.

We have a range of information technology providers who have been involved in these pilots. And I'm not going to name all the names, but it's a wide range of organizations that are supporting some of the largest facilities in the country and some of the smallest facilities in the country on a common transport mechanism. We have a wide set of EHRs, again some of the biggest names and some regional providers. Polaris EpiChart, for example, was an EHR that was developed by a consortium of primary care providers in Rhode Island who banded together and created their own EHR system, so the bigger names and organizations that are supported by physicians in a particular region.

And then there are a whole set of non- EHR clients that are supplying connectivity, they're supplying PHR connectivity, and then a range of modalities for information exchange ranging from basic EMO clients, RESTful APIs, and Web portals to the HIST.

All right. I'm sorry. We talked about the PHR; Microsoft Health Vault was an early adopter here. And then we have a set of lab providers who have been involved in the implementation pilots.

Okay. There are a lot of words here, and a lot of this is for offline reference. I'm going to start with overview comments, the first comment being that this is an exciting standardization effort supporting Directed Exchange. This is a huge value for providers who have marginal connectivity as a stepping stone for full connectivity. This is kind of starting from the basic and all the way up, in New York a representation that it's important to have scalability up to the more advanced forms of exchange, so the use of XDR and IHE protocols enabled high clinical workflow that allowed for robust interoperability and a high degree of clinical workflow and integration.

So really making the point that we can't stop at the simplest forms of exchange, we need to make sure that the information exchange model that we have scales from the simplest forms to the more robust forms with clients and organizations that can scale up to that level. So it's both a scale down and a scale up set of points.

In terms of implementation speed and difficulty. A bunch of experience reports that all amount to the same thing; it took anywhere from four hours on each side, to a day on each side, to a few weeks on each side. But getting the reference implementations up and running and getting to the basics of exchange we've got consistent experience across multiple different implementations that we've seen short timed implementation. A lot of the challenges in implementations have been relating to different operations, in particular, relating to content and vocabulary, and I think the transition from transport to content and workflow is a key theme that we've been seeing. We saw a strong focus in some of these communities on starting from transport, but really going into clinical integration/clinical workflow.

Again, similar comments; medium difficulty, no significant barriers, some issues about working with the existing corporate SMTP infrastructure. So as a note, a lot of the way that this works is for larger implementations where you're integrating this in with an existing infrastructure, the IT infrastructure for SMTP will involve an SMTP gateway that sits on the firewall, and then a whole bunch of specific installations that sit behind the firewall. And some of the complexity is making sure that you've got the routing in between your SMTP gateway, and the specific back-end supporting the direct protocol.

It depends on how much IT support you get in the process that can be fast or it can take a little while. And we've actually seen a number of implementations in high security awareness organizations that indicate that this pattern of gateway and then back-end systems is a pretty good pattern. It seems to work out pretty well; it's just a matter of educating the people who run the gateway about what you want to do. And I'm not going to go through all the rest of the comments here, but they're available. There are also more detailed experience reports that are available on the Direct Project Website.

So utilization and ease/difficulty, a lot of comments that all amount to the same thing. Once you get it up and running, it's simple. You need to adapt it to the workflow, and to the extent that it's integrated in the workflow, ongoing use is simpler. To the extent that it's a disconnected operation from workflow, ongoing use is more difficult. And I think that's for anybody who's been involved in information exchange, that's a familiar point.

Certificate management, we've seen a range of uses. This is an area that I want to be very clear about. A lot of the implementations have used a single trust authority and a single set of certificates. We've seen a range of experience reports ranging from we're using DNS for certificate distribution; it works fine—we've got two pilots that are doing that—to we are using a single trust model and rolling out certificates out to the providers, and that's working fine, as well.

Where that's going to fall apart is that'll work fine for community-wide information exchange. When you do cross community information exchange, we're going to need to make sure that we have good models for distribution and good models for certificate interoperability as the key factors for making information exchange work across communities.

Speed, this is something I think people have been worried about in terms of the SMTP infrastructure. Is the message going to go through fast enough? People who are able to stop by at HIMSS and looks at the direct area in the interoperability showcase saw a bunch of use of live interoperability. And the latency that I saw was seconds, sub-second latency. It's not real-time latency, right? It's not—if you're waiting for a screen to repaint it's not the right thing to do.

But if you're worried about five minute or 15 minute latency, it's not that. It's latency that's measured in seconds. And we see a lot of experience that indicates that over the internet latency is seconds, it's much faster than comparable fax transmission. If you think about how long it takes for a fax to go end-to-end through the fax machine, you can actually get the SMTP ... message there much faster.

In terms of workflow, again, the major theme here is that clinical integration, clinical workflow integration, content, and workflow are critically important for sustained interoperability and for sustained utilization. This is not a transport issue. It really relates to how well you integrate directed exchange into the core workflow systems that providers and patients and care managers are using.

Direct Ecos—this slide is a little out of order. So that's the experience report in terms of live interoperability. Highly positive, good experience—good experience in terms of latency and workflow. Good experience in terms of simplicity of adoption.

We have yet to test—and I want to be very clear about this—we have yet to test for what I think one of the critical aspects of Direct, which is use of Direct in a cross community model with lots of different uses of trusts, anchors, and certificates. I think the work of the privacy and security workgroup standards committee towards interoperable certificates is going to be critical to making sure that this scales from the community-wide level to the cross community-wide level. I think from a transport perspective, from a core specification perspective, from the early experience reports there shouldn't be any issues.

Where we're going to run into problems is where my certificate doesn't talk to your certificate, or doesn't trust your certificate. And my trust anchor doesn't trust your trust anchor. And making sure that we have those kinds of things worked out will be critical. I've said many times that policy and governance will be incredibly important to add on to technology to make this a scalable process across the country. That the conditions for trusting interoperability need to come from governance and trust that's established across the country. That's the only way we're going to get to wide scale interoperability.

Okay. In terms of the Direct Ecosystem I think one of the really exciting things we've seen over the last couple of months is a whole host of organizations of different types who have made commitments to implement Direct into their products. I want to be really clear about this slide. There's no endorsement of technology providers that's implied by this slide, and there's been no certification process for verifying that an organization got on this list. Organizations got on this list by self at a station declaring their intent.

That being said, it's a quite impressive list of both technology suppliers and organizations that serve smaller providers, that serve medium-size providers, that serve the largest providers of care in the country, as well as a whole host of states who have made Direct a part of their implementation, their approved implementation plans. There should be a little asterisk by this, because we took this list from the list of approved implementation plans that have been publicly released. We know there are more states that have Direct as part of their implementation plans. We know there are plans that have been approved where the states are also exploring Direct as an option, so the actual list is a little bit larger than this.

But I think you can see across the spectrum of EHR technology providers; HIA technology providers, HIOs, ..., statewide HIE efforts, personally controlled health records and health systems. A good list of organizations that have made reasonable commitments to deploy Direct.

And that brings me to the last slide here. One of the realities of upgrading really an ecosystem, making a major upgrade to information exchange of connecting that information exchange to quality care is that it

takes a while. Things take time. And what we're likely to see, what we're already seeing is some technology providers have business and technology models that allow them to roll out Direct very quickly. Some have models that require them to integrate Direct into an overall roadmap effort, release installed products, upgrade providers with those installed products.

And I think what we're going to see is through the rest of 2011 we're going to see a ripple of systems that are upgrading at different times with different capabilities. I think we're also likely to see differences over the next couple of years relating to information exchange generally of how well information exchange is incorporated into clinical workflow, which aspects of EHR functionality, directed exchange are incorporated into or not incorporated into. And the reality is that we've got—even if we said today, "Direct is absolutely the recommended option" we're going to see a ripple effect and roll out of capabilities over the course of 2011 into 2012.

So, really good early experience. A really good list of organizations that have made commitments to participate in an ecosystem, and just a measured reflection that it's going to take some time for that upgrade of capabilities to be universally available and roll out to all providers nationwide. And in some cases, more time to make sure that those capabilities are deeply integrated into clinical workflow and are coupled with the kinds of content and workflow standards that are necessary for, for example, supporting informed transitions of care to support patients that are medical home or accountable care organizations.

So, strong experience, very consistent experience. Two caveats to that experience, number one around interoperability certificates and number two around recognition that it will take time for making these capabilities available across the country. And as always—and the two people who've got their cards up—we need to recognize the Godfathers of Direct—Wes and David—for their early posts on simple interoperability, without which we wouldn't be here. Thank you very much.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Let me just start out with two comments—

Arien Malec – RelayHealth – VP, Product Management
Sorry. That's the Direct—I apologize, that's the Direct update. We can do the exchange and connect update maybe later?

John Halamka – Harvard Medical School – Chief Information Officer
Yes, why don't we just have some comments and discussions on this and then we'll go further. So, in my own experience of ... Direct, you've already said this, the issue wasn't Direct, it was the fact that I deliver two million emails through a secure, complex infrastructure with seven firewalls and anti-virus and spam filters and appliances. And now glue Direct into that complex infrastructure, it isn't totally plug and play. It's not a fault of Direct; it's the nature of the ecosystem in a corporate email system. So that's true. Then the certificate issue of multiple trust anchors, one trusts anchor, how is that all going to work? That was certainly an issue.

David, to your point about the challenge with HIEs and us having multiple approaches, I'll tell you here's one approach where Direct actually wasn't the controversy. So today I interfaced with Microsoft HealthVault, and I interfaced with Google Help, and I interfaced with Dossia, and all these other different PHRs. Every single one of them requires a totally different API. It drives me insane.

And so all we had to do with the Direct demonstration of Microsoft was I got an email address, jhalamka@direct.healthvault.com, and then we simply provided the patient's secure health email address to our EHR and it could send a copy of the record off. If every PHR vendor would just simply say, "We

support this. If you come to us with a secure health email address, we will send you a copy of your record within three business days," as is required for meaningful use stage one, it actually makes my life easier.

There wasn't, actually, because we didn't use the use case of displace an existing HIE or try to connect disparate EHRs. It was a simple PHR workflow that didn't really exist in a robust way yet. So, to me as we sort of think the 2011 experiments and pilots continue, if we get every PHR vendor just to adopt this, that will make 2012, as we get to more patient engagement and meaningful use stage two and three, a lot easier.

So, hey, let us open up to the Godfathers. I think you were first.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
John, would you put my card up? This is Dixie.

John Halamka – Harvard Medical School – Chief Information Officer
I will.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Thank you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David McCallie. First, Arien, thanks for a terrific amount of information packed into those slides, so required reading, I guess, offline, because there's so much data there. Second, John, to your points, I wish that Wes and I had saved the napkin where we had sketched out these ideas one evening before probably meeting number three or two of this committee. Because that was exactly the use case that we were addressing; is there are some simple, well understood needs that are not being addressed by the larger, more complex HIE world. And one of them was the PHR.

And as you recall, at that point I was advocating HealthBanks as an alternate, really, to the PHR. And the burden was how do you get the data from all those EMRs into the HealthBanks. And Direct was a direct consequence of a desire to solve that problem. The fact that is also solved some of these other more traditional use cases is a bonus.

But Arien, just a couple questions that you didn't discuss, or if you did, I missed it. The individual versus organizational certificates, what do you think will evolve as the right approach there based on current pilots? Is it too early to tell?

Arien Malec – RelayHealth – VP, Product Management
I think it's too early to tell. My belief is that we'll start with organizational level identity. There are some complexities to organizational level identity. In an organizational approach the organization has to a) vouch for all of the endpoints, and the boundary, the HIPPA boundary, for a variety of reasons is the organization. So in models where the HIPPA boundary is the organization, where the organization is the covered entity and the organization can vouch for level of assurance for all of its endpoints, that may be a reasonable model.

In areas where you can't make that level of assertion, I would recommend and think it would be a much more appropriate approach to go to individual level identity. I think as the ecosystem for identity in healthcare evolves, we'll see a shift where this is really a cost consideration issue. We'll see a shift from organizational to individual level identity. But we need to see an economic model that allows us to get there. So there's both a policy considerations—in some places the organizational identity works, and in

some cases it doesn't—and an economic issue in terms of the burden of providing individual level certificates.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
And one—I have a long list of questions, but I'll just ask one. When we designed this protocol, or the specifications, we worked hard to make it possible for an ordinary desktop email client to participate. Are you seeing anyone use that approach, or is it more Web based and embedded?

Arien Malec – RelayHealth – VP, Product Management
I think the predominant use is Web based and embedded, because it's much easier to control the security environment in that mode. So we designed it that way, it's still valuable to have designed it that way. I think many people, when they look at the complexities of managing HIPPA level privacy and security in an environment that involves individual email accounts elect to go a Web based approach.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Thanks.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So, first of all, on behalf of David, I think we have to apologize to all those people who woke up and found horse heads in their beds. I should have asked Doug earlier, but I feel like I missed a meeting. An acronym has mutated. We now have the PCHR. Is that meant to convey a semantic distinction from PHR, or is it just the normal—

M
I've heard it. I've seen this acronym creep in. I believe the distinction is between there's been a long distinction between a tethered and untethered PHR. The distinction is that a personally controlled health record is one that is under the control of the individual. It's an untethered health record. A PHR may be tethered or untethered.

M
The PCHR is really coined by the ... work done at Children's Hospital. It's just indicative that it wasn't bound to an institute.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, I had understood that the ARA sort of defined PHR as being untethered, but I'm just trying to keep up. I'm sorry.

So, coincidentally, before I came down here this morning, I got an email from HealthVault inviting me to get my personal mail ID. And I thought that was great, because I had HealthVault for a few years and all I've been able to get is my drugs from Walgreens into it. And I'm thinking about my doctor who's a rural family practitioner—two doctor practice. His wife is the other family practitioner. He'd play along with me and make this work, so what do I have to tell him to do? I think my options are he has to find an HISP such as the deal that's fronted by AFP. Or, he has to get his EHR vendor, which is a Cloud based vendor that I won't name, to offer Direct to its users. Is that right?

Arien Malec – RelayHealth – VP, Product Management
I think that's exactly right, and I think we're going to see both models play out. I think we're going to see EHRs that have exchanges as essentially a core part of their service. I think we're going to see EHRs that where you can plug the EHR into an existing exchange. And we may see models where you can do either.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, okay. So, I have to ask this next question carefully, because as a committee that advises ONC, we probably shouldn't be asking you to advise us on what we should advise. But, given the success and the

challenges that you've identified so far, do you see any obstacles to us making Direct a certification—a recommending to ONC that they may make Direct a certification requirement for stage two?

Arien Malec – RelayHealth – VP, Product Management
That is—what I think I would say is that we've tried to make sure that in the process we followed in the Direct Project, that we based the underlying implementation guide on well established specifications, IETS specifications that meet all the criteria of goodness for specifications. We tried to make sure that the process we followed was open and inclusive. We tried to make sure that we've vetted the implementation guide that we came out with real world implementation testing so that the material, the end material, that would be appropriate for a certification recommendation would be there for consideration.

I think the other thing to look at is how much of the stage one and stage two meaningful use criteria can be met through directed exchange? And my observation is you can actually meet that high availability and ubiquity directed exchange would considerably help in the achievement of meaningful use. And I think that's where I'll leave it. I don't know if you want to take it anyplace, or—

M
An excellent summary.

M
I do have a follow up to that, if you might. I've been sort of carrying with me the proposed stage two, and that may not be something we can comment on on this juncture until we get further guidance from Paula ... and ..., but it's interesting because you've keyed up the very second ... showing unit directionality and the requirement for stage two was for bidirectional exchange. Is reciprocal unit directionality the equivalent of bidirectionality? And beyond that really is the extension of the question in conversation earlier about then the relationship to broader synchronous exchange.

Arien Malec – RelayHealth – VP, Product Management
And I clearly, as I mentioned in the presentation, do not think that Direct is a be-all or end-all, or should is the destination. And, again, I think it's a question back to the committee as to whether it's an appropriate step in the journey.

John Halamka – Harvard Medical School – Chief Information Officer
And the group that's been evaluating the PCAST report did an analysis of all of the stage one exchanges, and it has made a statement essentially to the effect of stage one is really mostly about push. I mean, there are some elements that need prescribing, which are well known that are more query response kinds of transactions. But most transactions can be done in a directed fashion. So it will be interesting given that we, at the moment, have a couple of different ways of doing such push transactions, but will we offer more optionality, saying Direct is one of many? Or, Direct should be something that we strive to demonstrate, at least a single transaction in stage two. I'm sure that will be an interesting discussion of this group.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Well, based on your comment—what was it? Some of the standards aren't created, they're adopted, the one I use—and I think the underlying rationale for that is that the really governing forces for interoperability are economic and organizational, and so forth. The notion of certifying for something then sort of opens the playing field for that competition on actual choice to come forward.

And then I guess that this conversation has more or less encompassed my third question, which is to say are we—if we were to be recommending certification of Direct exchange, it probably should be certification to do something. That is, it's awful easy to say, "Yes, they can." There ought to be some level of functional requirement; you receive a document, it becomes available in the workflow or something like that. Or you send a transition of care document, or something like that. That's what it's actually certified for. I'm not actually asking you to comment on that, I just wanted to make it clear. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Sure. Now Dixie, I know you had a comment.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, thank you. It's a little hard for you to see my card. This is Dixie Baker. Thank you, Arien, that's a really good update and very nice progress, obviously. I think my question may relate partially to your comment about policy and governance, and partially to Wes's comment just now about certification in stage two.

During our most recent assessment, we expressed some concern about the optionality that is offered by Direct, and I think we've seen some number of demonstrations of how the optionality is being exercised in your presentation today. You'll remember that when we completed that assessment, you told us about a document that was in development that would clearly define Direct branding; in other words, what it means to be Direct compliant. And the thought was that given all this optionality within Direct, that such a document would clarify the minimum requirements for an entity to declare itself Direct compliant. And it would also clarify the difference between using SMTP and S/MIME and being Direct compliant.

So, I'm wondering what the status of that document is?

Arien Malec – RelayHealth – VP, Product Management
I should have mentioned that in the presentation. It's pretty close to final. It is the—for the compatibility document I think we're now calling it. And the English language version of it is that it's a little bit like the telephone. I may be using a VOIP line, you may be using a traditional land line, and somebody else may be using a variety of different standards for mobile telephony, but we don't call it a telephone if we can't call each other. And it really defines that common sense notion that you don't call yourself Direct unless you can get the message from Point A to Point B modular trust and that the common specification in all cases is the SMTP and S/MIME specification.

That's the specification that defines the baseline for interoperability and the common baseline for getting something from one point to another, which doesn't mean that local transport in a community all needs, at least the way that document is specified does not mean that local transport in the community needs to follow that specification. Again, I think we're seeing example uses where local exchange in the community is currently being done and currently being done at a high level. It provides the condition such that local exchange, that the local participants are addressable and that other addressable participants outside the local exchange can send and receive to those addressable participants. So again, that is the compatibility document and it's currently going through final consensus on the Direct project.

Some of the comments that the Projects and Security Workgroup commented on its very helpful review related to really policy issues relating to content and some useful baselines for content and there's a best practices document that's working its way through the best practices work that we're doing to define at least some common modes for lowest common denominator transport in ways that allow for and really promote higher common denominator transport where it's available.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, thank you. Thank you.

Arien Malec – RelayHealth – VP, Product Management
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any other questions on this particular topic?

M
One comment and a question; some services that are communication centric, when you try to operate them, the first thing you do is ping a test server that can respond back and basically say, "Yes, I got your

message and here's what you sent me; looks good." Skype and other ones let you do that so you can make sure that the issues that you're running into aren't firewall issues or whatever.

I wonder if there's a role for a Direct test server, a ping server that could validate a number of the core use cases so that people who are, as they're bringing systems up, could at least verify that they pass a common test server that's hosted by ONC or NIST or maybe even a private entity, but has that ever come up for discussion?

Arien Malec – RelayHealth – VP, Product Management
It's certainly come up for discussion. I think in the absence of it being a certification criteria, we need to look at what mode we'd have to host that internally. I think it would be certainly a useful community add for somebody who wanted to operate that. It's actually pretty cheap to do. There's instructions for how to take a bare Infrastructure as a Service machine and bring it up and running on a Direct transport.

M
There's a business opportunity there for some of us.

Arien Malec – RelayHealth – VP, Product Management
That's right.

M
The next Nationwide Health Information Network; now one question, how do we pronounce the new acronym.

Arien Malec – RelayHealth – VP, Product Management
There is no new acronym.

Jonathan Perlin – Hospital Corporation of America – CMO & President
It's pronounced Nationwide Health Information Network.

M
Okay, thank you. Just for the record, I'm glad that there's no acronym because I'm suffering from PACS. Does everyone know what PACS is? It's Progressive Acronym Confusion Syndrome.

John Halamka – Harvard Medical School – Chief Information Officer
So, I think this is kind of a good segue in the sense that as we look towards the future, realizing that when we look at vocabularies, we want to pick the right vocabulary for the right purpose and the right task and not to overload a single vocabulary into all those different possible ways that you could use that vocabulary. I think we have with Direct some very clear use cases and some very clear purposes for that, but isn't intended to necessarily satisfy every possible way in which you might exchange information.

And so, at the last meeting we were asked actually to also provide an update on the Nationwide Health Information Exchange and CONNECT and given some of the announcements that have been made with the Olympic Foundation and others, I thought it's an opportunity for us to, although just very briefly, provide the committee an update of what's going on there.

So, with regarding to that, Nationwide Health Information Exchange, there are ten current exchange participants that have served as the core for some of the implementation pilots that are ongoing. I think it's important to note that there will be a near tripling of participants in the Nationwide Health Information network over the course of the next year or so. We actively have nine applicants that are composed of beacon communities, state HI agency MS and their partners, that are going through the process of qualify. We have certain teams that are going through the steps of validation.

So, qualification just basically says, “Do we have all the right legal agreements and things like that in place?” Validation says that we’ve actually gone through and tested to make sure that they conform to the specifications, and that includes seven SSA awardees, three beacon communities and three states. We’ve got five SSA awardees that have actually gone and been added into the network.

We’ve received a number of inquiries and one of the things that limits our ability to take new folks into the Nationwide Health Information Network Exchange is some of the restrictions that the Office of General Counsel or GC has placed on participants and the need for them to have some sort of contractual relationship with the federal government. I’ll allow Jodi to explain all of that offline if need be.

One of the things that we’ve been working on is establishing governance. In the High Tech Act, there was an obligation that ONC establish a governance mechanism for the Nationwide Health Information Network. And so, we are in the process of putting together the background and the discussion so that we can generate a rule that will allow us to address some of the governance issues. We’ve received recommendations from the Governance Workgroup and from the HIT Policy Committee regarding scope and focus, and we expect that around the same time as we get the CMS rules, the standards and certification criteria, we’ll also be working on a governance rule that will help provide some clarity there.

It’s important for us to do this because it helps us both addressing some of the issues of exchange. We can’t really expand exchange until we’ve got governance in place and that provides a mechanism that will satisfy some of the OGC requirements. Currently, those people that can participate have to be under a federal contract, a grant or a cooperative agreement.

I think the role of governance in all of this is not only to provide that expansion, but to provide two things; to provide the conditions of trust and to establish sort of the conditions of interoperability. Those are two real clear focuses that we have within governance.

Right now, states are establishing sort of governance roles and I think it’s important from the goal to have a Nationwide Health Information Network to have some of the governance available. It will provide the necessary transparent oversight, enforcement and accountability that we need to establish those conditions of trust and interoperability.

The Governance Workgroup recommendations include nine principles for governance. We’re not going to go over all of those today, but the goal here is that the federal government should support and provide strong incentives that will promote sort of the adoption of those principles as well. There is the need to have some shared governance responsibility and conditions of trust and interoperability that verify that those conditions have been satisfied. And so, right now, we’re working through how ONC can construct this rule and assure both accountability and oversight of the governance rule.

So, that’s by sort of way of sort of an update of some of the activities that are going on. We’re continuing to bring people onboard into the Nationwide Health Information Network and we’re working with the background and the other things to develop a rule that will help expand the participants. Again, this is anticipation of broadening and having more robust exchange and recognizing that Direct solves really important, really critical problems, but we want to make sure that we have an opportunity if there are broader problems, such as query and retrieve or other things, we have the tools and infrastructure available to help with that.

With regarding to CONNECT, remember that CONNECT is the application or the tool that takes the Nationwide Health Information specifications and creates a way of kind of implementing those, the

gateways and the profiles. We have a contract through the Federal Health Architecture to do CONNECT development. That's supported in large part by our federal partners. That contract was protested and so we have, however, continued to take the advice of our federal partners to expand the ecosystem of developers that are working on CONNECT.

So right now, rather than having a single developer, we have been working with MITRE to develop a shared development environment in CONNECT so that that's accessible to our federal partners and to others that want to develop new functionality within CONNECT. We also have a contract to AEGIS that is supporting some of the virtual lifetime electronic records activities or the VLER project.

There's an emphasis there in supporting some of the short-term priorities because our VLER participants that are using the Nationwide Health Information Network for the project has some very, very clear time lines that need to be addressed, but also to work on a longer-term testing strategy to make sure that we are satisfying those conditions of interoperability. As you expand the number of developers, it becomes increasingly important to have testing as part of that.

We've hired some new program leads and we've continued to have some ongoing release cycles, one in February and anticipating having another one in June with some additional updates. We're trying to work to develop an automatic and automated testing environment that will make it easier for folks to onboard so that we have this notion of being able to ping an environment and see if you're reading to bring things onboard, and we expect that the contested CONNECT contract should be resolved within the course of the next month.

With regard to some of the open source development, back in December, we convened our federal partners and really began talking about how we can expand the participation of the open source community. One of the issues there is that it's been used in the past as a distribution mechanism, but not really as a community in which there's sort a bidirectionality between work that's been developed in the open source community to be used within the CONNECT project.

We have been working and operationalizing that plan and just a week before the HIMMS conference, we were approached by Dave Riley and Vanessa Manchester, both of whom were formerly part of the CONNECT team, that they were starting a new nonprofit called the Olympic Foundation and they were going to begin by using the CONNECT 3.1 release as their baseline for future development.

And so, what they've done is they've taken the CONNECT 3.1 release, they've renamed it Arion 3.1, and are working on developing a new release called Arion 4.0 that includes some of the things that we knew from over the course of the last couple of months needs to be improved and fixed. But until we get our new contract awarded, there is the possibility that there may be a divergence in the code base.

Now, it's important to recognize that Arion does not replace CONNECT. We have ongoing development activities and we anticipate actually supporting VLER and supporting our federal partners in a more distributed development environment that includes the open source communities. We expect to be transitioning to that more distributed environment with the open source communities, but I think what we see as the important role of ONC and the Federal Health Architecture is to make sure that we establish high quality modular implementation specifications and robust testing so that if somebody takes those specifications and they decide to do it in a Java-based approach using CONNECT software, that's great. If they want to do it in a .NET, that should be something that we would encourage, and if they want to do Ruby on Rails, which is Arion's favorite, we also have that ability as well so that what is important isn't so much the code base or the particular language that it's written in, but that we've got clear implementation specifications and robust testing that assures that we have that interoperability.

So, CONNECT and Arion both properly implement those Nationwide Health Information Network standards and specifications. They should be interoperable, even if there is a change in the code base and the way in which the code is being constructed.

So, that's sort of an update on that. We are continuing our development efforts. We're continuing the exchange. I think we need to take lessons learned from the Direct project in terms of simplicity, in terms of modularity, in terms of focusing on sort of those endpoints and make sure that we apply to those to all the work we do, including the work of the Nationwide Health Information Network and CONNECT.

M
Is that a new question you have? Very good. On the governance process, the one that matters, the one that will result in a rule, who will fall under that rule? Is it just the people who are working as federal partners on the current instantiation, maybe Jodi, I should be looking at you, of exchange or will it be anyone who implements the protocols and second question, does it include Direct? It sounded like you implied that the governance would involve Direct, but I wasn't sure that I heard you correctly. Really, the broad question is who's going to be governed by the rule?

John Halamka – Harvard Medical School – Chief Information Officer
I can let Jodi—policy and technology, we're working together. So, I'll take a first stab and then you can correct me.

Jodi Daniel – ONC – Director Office of Policy & Research
Then I'll correct, right, yes.

John Halamka – Harvard Medical School – Chief Information Officer
I'll make the policy assessments and then Jodi will kind of assist me in some of the technical details. The rule is intended to be voluntary. It's not going to be a mandatory designation. I think we're still kind of working out whether this is something that is a brand or if this is something that is a criteria that you can say, "We've met all of the criteria to be able to exchange."

I think it fundamentally has to go to the conditions of trust and the conditions of interoperability, that somehow when you are subject to governance, you also have provided some level of assurance maybe above and beyond someone who said, "Well, we just use the things that we've implemented," some sort of recognition that you satisfy those conditions of trust and interoperability.

Jodi Daniel – ONC – Director Office of Policy & Research
So, part of it is that we are, in fact, working through drafting a proposed rule. So, we don't have all the answers and even when we have some answers, they'll still be proposed and we'll get a lot of comment….

The Policy Committee did struggle with the scope of the question. So, I don't think it's sort of completely—it's not completely nailed down even from the recommendations perspective. We are looking at what services to bring in. I think it is safe to say that we're not looking at this just as a governance of the exchange project. The statutory language was governance mechanisms for a Nationwide Health Information Network, not for a particular project. So, I think it's safe to say that we're looking more broadly and trying to figure out how all of these pieces sort of fit in with our governance structure.

So, I think you nailed the most challenging thing, which is to figure out what the scope is, who's covered by this and how you then apply rules regarding trust interoperability that would apply to a scope of maybe of some … and different players without either dropping the bar too low in order to bring everybody in or making it too high so that folks were doing more simple services…. So, we're sort of balancing all of that.

M
So, it could end up including Direct, but not yet determined.

John Halamka – Harvard Medical School – Chief Information Officer
I think it's about the conditions of trust and the conditions of interoperability. Remember, we've defined—the Nationwide Information Health Network working group sort of defined that to be the standard services and policies that allow that kind of exchange to occur.

One would hope that if we have a modular approach to what those standard services and policies might be that Direct may be one of those things that would fall under that umbrella. I think it's safe to say that it's not limited perhaps to what we would call the current exchange model that we've got right now. I think as part of the rule making process we're trying to make sure that we address conditions of trust, conditions of interoperability wherever they are with regard to the Nationwide Health Information Network.

M
Thank you. So, I guess, first of all, I just wanted to point out that on the current exchange participants who are in production, there are both CONNECT and non-CONNECT gateways interoperating, working just fine. In fact, for my own organization, we're currently in production in multiple states with internally developed software not using CONNECT and frankly, found meeting the specs was relatively easy. So, in case anyone has got this fear that code divergence means non-interoperability, currently in the VLER project and in the exchange that's in production, there are multiple gateways from multiple code writers that are being used.

I also have a question related to sort of the renewed development of CONNECT and I wanted to reflect back on one of the things I think we heard from Dr. Blumenthal last year that there was a desire to "get the government out of the software business." I think that having ONC basically hire new developers and project managers and so forth, they represent a change in direction. So, I wanted to ask you is that a change in direction or—

John Halamka – Harvard Medical School – Chief Information Officer
No, not at all. The issue is is that we have a number of—without going through all the gory details, the money for the CONNECT recompete is resources that we have been entrusted with in terms of the managing partner for FHA and for CONNECT. That's not ONC money. That's really the federal partners.

Part of this is to help transition. We are beginning to, and I hope it came from the presentation—our responsibilities and our focus needs to be on getting high quality specifications and testing to make sure that those conditions are being met. We don't want to leave our federal partners without any sort of visible means of support and so we need to provide a transition path for them. Much of the federal partners budget three years in advance and so there are ongoing discussions to make sure that we have an orderly transition, that we are able to support, I think, getting back to our core mission around testing and around developing those high quality specifications, but being sensitive to the federal partners who are invested in those tools to make sure that as we do that, we do that in a way that's not disruptive to the VA, to DoD and the other folks who rely on that right now.

So, I think there's been some confusion out there that says with the announcement that was made two or three weeks ago that we are abandoning all the work that we've done before. I don't think that that is a correct characterization. I think what it is is we've got some things in the pipeline that we need to make sure we have an orderly transition around and that we provide a mechanism that we can be responsible with those resources that the federal partners have to support the CONNECT work.

So, it's not a change in direction, but it isn't also sort of precipitous cliff. It's the beginning of our glide path I think to provide a transition to a new model in which it's more distributed, there's an emphasis on the testing. And so, the kinds of things that are happening in the open source community, those are all good things, but we want to make sure that we provide kind of a path with our current resources and the current constructs that we have to get us to that without dropping the ball and creating problems.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Chris Ross.

Chris Ross – SureScripts – EVP & General Manager of Clinical Interoperability
This is Chris Ross with SureScripts. Before I comment, I just want to know; I may have a potential conflict of interest here that I want to identify because my organization is involved in commercialization of exchange on top of the standards. So, that disclaimer aside, hopefully I can quote some other people to sort of talk about this.

I note one thing which is ours is not the only organization that's working on the commercialization of exchange. There's an awful lot of private sector investment that's happening in this space and I think that's a great thing. …for example has pointed out that federal government setting standards that then creates private initiative is a good thing and we want to encourage that. I'm also one of these people that believes that Nationwide Health Information Exchange ought to be considered as all inclusive of exchange, CONNECT and Direct and that we shouldn't have a strong rule around something that might be considered as sort of federal technology as opposed the rule boundaries stopping and not including those areas that would engage private investment.

So, I heard the answer, Doug, that you gave before and I think I agree with them. I think it will simply create a much cleaner and easier to understand marketplace if the rule is really inclusive of all three of those different types of transport mechanisms. Jodi, I think you're saying the same thing. I just want to really underline that in part because organizations like mine sometime get questioned or accused about trying to do things in a proprietary fashion and that's what we don't want to do. It is more helpful to us if we can operate with a role and within a set of standards that are governed in a consistent fashion.

John Halamka – Harvard Medical School – Chief Information Officer
I think those are very helpful comments and quite frankly, that's why I wanted to emphasize it's the conditions of trust and the conditions of interoperability, the importance of high quality specifications and robust testing and that anything that falls underneath that, which I think is CONNECT exchange, Direct and maybe other things that we need to assure those two pieces is the part that we want to include.

M
There was discussion earlier about diversions of standards and those kinds of things. I think it's important to note that if you look at the Nationwide Health Information Network as an inclusive model there are patterns of exchange, for example, for ePrescribing that do not currently fit the existing set of exchange specifications and it's important to make sure, for example, that standards for privacy and security are inclusive of the different modes of exchange.

M
Well, in some instances, a new rule may not be required, right? I mean there's statutory authority for ePrescribing and how that's handled and what standards may be used under … Modernization Act and so on and so forth. But in any case, there is a consistent standard under which both public investment and private investment and private and public activity happens today, absolutely.

M
Thank you as well; I mean a terrific presentation, just very engaging in terms of future direction and the convergence of the interoperability with the use of the systems. Again, I'm going to implore, and it's really sort of not a note to you so much as a note to ourselves as we contemplate the standards to support, there's really a glide path for those people who are trying to move forward under the progressive requirements of…. One thinks about exchange and proposals for stage two or the three providers, stage three, or the notion of 30% and clearly, when one's talking about 30% of a complex referral network, it's not going to exclusively rely on Direct.

And so, the ability to have a glide path, a set of standards that's built will really, I think, identify for us a scope of work to support you and the Policy Committee in terms of a trajectory that is one that the broader ecosystem can embrace, committee to, and move forward on.

John Halamka – Harvard Medical School – Chief Information Officer
The consistent themes there about standards, but choice, that implementation should be decoupled from standards, we should have good testing platforms and certification, in fact, should allow us to have multiple instantiations, open source and commercial that are going to accomplish the policy goals that will be outlined in stage two and stage three. The conversation in that area and that Dixie had about compliance and best practice, where can we use the brand and what does that mean is also related to this discussion.

So, I think the fascinating body of work for us all as we look forward to the Office of No Summer is might we as we think of the certification rule that comes out with stage two have such statements as you must be able to exchange one transaction using this method - Direct exchange, CONNECT, whatever it is that says for a certain kind of transaction.

So, I mention this notion of the PHR use case as one that doesn't seem too controversial because there isn't a huge amount of exchange happening yet. And so, imagine how the ecosystem could suddenly explode to become more patient-centric if every EHR were capable of sending at least one transaction to a PHR using Direct. I can't answer the question today, but it certainly is food for thought. So, thanks very much for a great discussion and I look forward to, Doug, as we work together over those next six months and getting the work plans to get all the work you need done in time for your deadline.

I know we have one last item before lunch and that is Quality Workgroup. I'm happy to introduce Jim Walker who has agreed to assume the mantle with Karen Kmetik of the chairmanship of our Clinical Quality Workgroup. So, as folks recall that there is a great desire to retool, to make sure that we provide a parsimonious description of quality metrics that are straightforward to implement and that we measure quality in support of policy and do it in a way that creates the least burden possible for all our hospitals and eligible professionals.

We transitioned the leadership of this workgroup because there's going to be a whole new body of work of which the NQS is going to be an essential participant in and to have the group providing oversight and recommendation, chaired by the organization that is providing the service didn't seem to be the best of all

possible constructs. So, Janet agreed that it would be great to have new leadership of this group and Jim has volunteered; so look forward to your update.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thank you, John. It'll be brief today. As you can see on the next slide, we have a stellar group of members of the committee, which has not met yet. We're hoping to get someone who can represent long-term post-acute care so that what we design, even though it doesn't include them directly in meaningful use two or three, is extensible to a system in which they are part of the healthcare team.

We have been working on the scope of work with Tom Tsang and Doug Fridsma and Karen, and we'll be meeting for the first time on April 7th. Floyd Eisenberg graciously has given Karen and me a review of the quality data model and such, one of the things that we'll be addressing early in our meetings and here … the report.

M
Any questions?

John Halamka – Harvard Medical School – Chief Information Officer
Sometimes when you say you hate to between you and lunch—so again, look forward to as your group comes forward with recommendations and to the extent that I have just gone, as I mentioned, through certification of both the hospital base and the ambulatory certification processes including all the quality metrics and the PQRI, XML and all the rest, I implore your notion of where we can make exclusionary criteria optional at the discretion of the implementer, that this would certainly be a good thing, that we ensure that the data elements that we select are those that are represented in an EHR and pay attention to the workflow and the cost if they aren't directly in the EHR today.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
That's definitely on our draft scope of work.

John Halamka – Harvard Medical School – Chief Information Officer
Well, questions/comments? There was little controversial that you said.

M
(Hard to hear speaker)

John Halamka – Harvard Medical School – Chief Information Officer
Okay.

Jonathan Perlin – Hospital Corporation of America – CMO & President
It's just a comment. From the very beginning, this is really the end stage of the evolution from structure to process to outcome and support of better health of the population, better care of the individual and better value. I know that Jim and the folks on the committee have made terrific contributions in that space and so, the overall framing is really in that context.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you for your brevity. I'm sure everyone will appreciate a couple extra minutes for lunch and … to people online, let's reconvene sharp at 1:00 and thanks, to all, for robust participation this morning.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, thank you and many thanks to everybody for reconvening today. I appreciate the work that goes on not only at committee, but importantly the work in between within the Privacy and Security Group. The Privacy and Security Group has been working to not only build in the broad sense the trust fabric, but working to build consensus in process as we move toward the requirements for stages two and three.

We have Dixie Baker online today and Walter Suarez here in the room with us. Coming out of this, we do have an action item, which is to consent or otherwise the recommendations on digital certificates that have been the work of the group the recommendation to bring us today. One of the areas that we'll have some discussion about the state of activity is on the area of provider directories. This is one of the areas where, frankly, we need to be sure that all the questions that are asked on the state of activities is sequenced with the Policy Committee. But in the broader sense, as we get started, during the lunch hour, John, you made an observation, which I think is just so on point. Let me turn to you how we might sequence our work over the next set of meetings.

John Halamka – Harvard Medical School – Chief Information Officer
So, as I look to some of the more successful workgroups in the Standards and in the Policy Committee ecosystem, what they try to do is give a calendar that says, "The month of April, we devoted to the discussion of device standards. The month of May will be devoted to individual level provider directories;" that is you publish a calendar of the four or five critical topics that we want all of us to be thinking about because if we're going to hit December or whatever deadlines you tell me, October, we better have covered every topic you need between now and then. And so, I just hope coming out of Doug's planning activities, as you look at your "I must deliver this by a certain date and back us up," that we could together formulate monthly schedules ahead of time.

Just as we turn now to Dixie Baker, remember that if we are going to implement a Direct as we've been talking about, or exchange or CONNECT, you need a trust fabric. You need a standard, technical standard and you need policies around the use of certifications. So, we actually heard as Arien went through his examples of where some of the challenges were in Direct implementation of do you have one trust anchor or do you have multiple trust anchors, how does this work exactly? Oh, but wait, there's the federal government and what if, Karen, I want to send you a transaction? Do you trust that Ding Bat Certification Authority is okay? Maybe you want me to have some sort of relationship to a federal certificate authority that you trust.

There are many, many policy and technology questions and so, Dixie and her group and Walter have been asked, okay, we need a trust fabric. Certificate standards are important. What do we do? I'll turn it over to you, Dix.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
We are the trust fabric producer I suppose indeed. So, Dixie, I'm going to turn it to you and I think you wanted to cover the first parts.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, all right, thank you very much. Thank for you allowing me to dial into this as well; I appreciate it.

This is the members of our workgroup and I just wanted to point out that we have a new member, Lisa Gallagher, who is the HIMMS Senior Advisor for Privacy and Security. So, we're very, very pleased to have her as a member of our workgroup. I want to thank the efforts of everybody else on this list as well in putting together the recommendations that we're going to present today.

You might look at what we are presenting today as kind of a pilot for the new process that John Halamka introduced at our last meeting and I'll go over that very briefly just to establish the context. The Privacy and Security Workgroup has been charged to produce recommendations for two standards. One is a digital certificate standard and the second is enterprise-level provider directories. We are going to give you our recommendations on the digital security standard today and we'll give you an update on our work on the enterprise-level provider directory.

Okay, this is my simplistic view of kind of the swim lanes of the new process that John described in our last meeting where you may recall at the very end of our last meeting, John mentioned that the role of the HIT Standards Committee is changing a bit from really doing the detailed specification of standards to rather defining requirements that those standards must meet. Then the job of actually specifying the standards themselves is the job of the SNI framework that Doug Fridsma spoke about briefly earlier today. So, as I mentioned, we've been given the two standards to specify the requirements for. One is digital certificates and the other is enterprise-level provider directories.

Okay, so the first presentation about digital signatures is divided into three parts. The first parts are the delivery of this, exactly what the charge was, are the requirements for a standards for digital certificates. I am including a bit of a tutorial about digital certificates in this section for those who are not as familiar with what certificates are all about, what comprises a certificate and what it's used for. Then the second part of our recommendation is the recommendation for further investigation and then the third is a recommendation for a question to be given to the Policy Committee.

So, with that as setting the stage, first some basics about digital certificates; a digital certificate is basically an electronic document that certifies that a person or an organization or a Web Serve or an application, whatever, has been issued a pair of encryption keys are mathematically rebated in a way that allows you to encrypt with one key and decrypt with the other. What's interesting, and this is commonly called public key encryption or asynchronous encryption, asymmetric encryption. What's interesting about this is that you can use either key to encrypt so long as you use the other key to then decrypt it.

One of those two keys is published like in a phone book or anything. It's just open for anybody to see and that's called the public key because it is digital, and then the other key is kept secret by the entity or the person or the organization that the digital certificate has been issued to. That key is called the private key.

Digital certificates are issued by something called a certificate authority or a CA and they're digitally signed by the issuing CA or the issuing certificate. So in other words, they're signed using that CA secret or private key. The CA certificates themselves are either self-issued; so a CA can just issue its own certificate and they can be self-signed and self-issued or they can go to another CA to get their certificate and that's whether they self-sign it or whether they go somewhere else. The requirements of where you get a certificate are really a policy issue and not a technology issue.

Certificate authorities periodically publish something called a certificate revocation list or a CRL and that list identifies the certificates that are no longer valid and that have not expired. You may have, on occasion, tried to run an application that you'll get a message that says, "This digital certificate has expired. Do you want to run the application anyway?" What has happened there is that the system has checked the digital certificate associated with that application and is telling you that whoever signed it, their certificate has expired. It's up to you whether you want to take the risk or not and that the Web Server has checked the CRL to see whether that certificate is still valid.

Certificates are used for a number of purposes, one of which is to authenticate the identity of a person or an entity using this challenge response type of a mechanism. In other words, you say, “Here’s a word that I’ve encrypted using your public key. Let’s see if you can decrypt it using your private key and if so, I know that’s who you are.”

They can also be used to digitally sign a message or any other transmitted content, which is a digital signature, and they can be used to share a secret key to be used for exchanging high bandwidth data. So, if you’re going to exchange a data over a period of time, you’re better off to use a single symmetric key rather than public key encryption for that purpose, but to use public key to wrap up the secret key and send it to your friend and say, “Okay, here’s a secret we’re going to be using to encrypt this data.”

As you might expect, the trustworthiness or how much you can really trust a digital certificate is directly dependent on how much you trust the entity that issued that certificate or the certificate authority. That certificate authority can be at the top, the top certificate authority of a public key infrastructure as in the federal PKI, the CA that issued that user’s own certificate or any other trusted CA that they decide to trust.

In the practices that a CA is using to issue and manage certificates are described in something called a Certification Practice Statement or CPS. That really is one indicator of how trustworthy that organization is. If the CPS says, “Well, we’re a process-making organization, we’re in this game to make money, so whoever asks us for certificates we’re going to give it to them and we don’t really require much proof of who they are,” you’re not going to trust them very much. So, the CPS is really important to judge how much you’re going to trust that certificate authority.

CPS, the Certificate Practice Statement, can be certified by organizations and they are certified by organizations such as the European Telecommunications Standards Institute and Web Trust and they also can be certified by certain communities such as the SAFE-BioPharma, which is a PKI for the pharmaceutical industry and the Federal Bridge Certificate Authority, Federal Bridge for federal exchanges.

Okay, this is a picture where I’ve tried to illustrate two different trust models because digital certificates can be the sharing of information and deciding who you’re going to trust. Whose digital certificate you’re going to trust depends on the trust model. On the left, you have a hierarchical public key infrastructure where you’ve got Bob there as one of the users and in this hierarchical PKI, these are the most straightforward and basically Bob trusts everybody who is in that same PKI because he knows that everybody in that community has undergone the same level of scrutiny before their certificate was issued to them. So, he knows that their certificates are as trustworthy as his own certificates.

On the right, we have something that we call the multi-route model and this is more the model that’s used by the Direct project that Arien talked about earlier today and here, you have user Alice up there who trusts the certificates issued by her own trust anchor or her own certificate authority and she trusts the certificates that are issued by other trust anchors that she thinks are trustworthy. So, you’ve got over there the trust anchor to the right. She knows who that is. She knows what their certificate practices are and she trusts everybody that it issues certificates to.

So, you see it’s not just a PKI-to-PKI. It’s not that she trusts everybody even in her own hierarchy, but she trusts everybody who gets certificates from certificate authorities that she trusts. That’s why it’s called it a multi-route or we call it the multi-route model.

This is some of the basics. The digital certificate can include a lot of information, but what you have here are some of the basic content that a digital certificate includes. As I mentioned, it's signed by the certificate authority that issues it and it has version, it has a serial number. It has a period of time that the certificate is valid. It has the name of the subject, which may be an organization. It can be a software application. It can be a person or whatever. This is where the subject's key, public key is published. So, it's openly for anybody to see in that certificate. Then you have optional extensions that may be included in the certificate.

So now, are there any questions about what I've gone through so far?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Dixie, this is Jim Walker; just one quick one. How does Alice know which of those trust anchors can be trusted? Presumably, she has a life.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, she's more likely to trust—I'm going to back to this picture. She's more likely to trust this user down here. She may know this user down here and know that this user got his certificate because he's a guy, got his certificate from a trust anchor that she knows, like that trust anchor might be the HISP—well, let me not use the HISP. I may know that David McCallie got his certificate from Cerner and I don't really know Cerner, but I know David McCallie and I know David wouldn't be getting a certificate from somebody that he didn't trust and I trust his judgment, so I trust other certificates that Cerner issues.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
But if I'm going to be part of a network that has maybe scores or hundreds of trust anchors, it would seem to me there'd have to be some kind of regimen, a regime that would govern all of them, that I would trust that rather than trying to know about all the trust anchors.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Very good, Jim and you are making a recommendation in that area right now. That's because you're asking—that's a policy question and that's a very good question as well. So, good.

John Halamka – Harvard Medical School – Chief Information Officer
John Derr just came up with actually the best explanation of the multi-route model. It's Facebook.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that's right. Very good. Okay, here are our recommended requirements, and I have to tell you; one of the toughest aspects of this new model of doing things is deciding the level of granularity your requirements are going to go to. We're used to getting to a pretty fine level of detail on what standards should be and now, the HIT Standards Committee's job is to really tell the SNI framework what the requirements are for those standards.

We got a bit of experience with it in this when we evaluated the Direct project where, based on early briefings about the Direct project, we established our requirements, that it would be simple, direct, secure and scalable. Those were our requirements that we sort of established for our evaluation. Under the new model, we establish the requirements and the criteria we're going to use to do an evaluation like we did for Direct, but we specified them up front. I believe that all of us will run into this kind of tension into just how far you go with the requirements before you hand them over to the SNI framework team.

So, this is our thought at digital certificates and I think digital certificates will probably be one of the easier cases we'll get simply because just about everybody uses X.509 as the standard for digital certificates.

So, it was pretty straightforward. For example, the NHIN CONNECT uses X.509 certificates; Direct, HISP use X.509 certificates. So, it was pretty straightforward that one requirement was that the digital certificate standard must conform to use X.509 version 3, Certificate Profile.

The second, we wanted the digital certificate to support both Direct exchanges and the Nationwide Health Information Network Exchanges. And so, we put that both of them, both certificates for Direct and certificates for the Nationwide Health Information Exchange, must include all the basic certificate fields which are basically what are those that I showed you in the envelope a while ago. We had considerably discussion around the standard extensions. There are a number of standard extensions that are defined in RFC 5280, which is the X.509 standard.

You could go down to a very fine level of granularity and say, "The following extensions are absolutely required for a Direct certificate," but you can easily over specify digital certificates so that they're not more generally useful to you. So, we left it as that it must include those standards that are needed to support SMTP and S/MIME for Direct. In other words, it has to have the extensions that are needed for regional authentication and for digital signature and for finding the certificate authority; those kinds of things. It may include additional ones, but we did not specify exactly which ones should be included. The same thing for the Nationwide Health Information Network except it's for the extensions needed for transport layer security or TLS connections rather than the S/MIME e-mails.

We also said that the certificate revocation list must conform to X.509 version 2, the Certification Revocation List Profile and that profile does support a difference. There are two ways to really get the certificate revocation list. You can either download the whole thing or you can just do a query for the certificate using something called Online Certificate Status Protocol. The same standard supports both.

We didn't want to constrain whether there would be one standard or two standards. So, we explicitly stated that nothing in these requirements would preclude the specification of a single standard for a certificate that could be used for both Direct and Nationwide Health Information Network Exchanges. We know that, for example in the case of the VA, they use a different certificate for their Direct exchanges versus their NHIN CONNECT exchanges, but there's nothing there that really demands that that be the case. So, we want that to be part of the standardization activity under the SNI framework that we look at at whether we need two standards or one standard.

Okay, and our evaluation criteria are pretty straightforward. They're just ways to see whether the standards conform to X.509 version 3, whether it includes the basic certificate field, and these are just questions that we could use downstream when we're given the standards from the SNI framework team to evaluate. These are the questions we will ask and make our evaluation judgment based on these. Okay, questions?

John Halamka – Harvard Medical School – Chief Information Officer
Yes, so Jamie has a question.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Hello, Dixie. So, my question is this, and I know that there are certainly exchanges that use digital signature which you mentioned where they use the private key to encrypt the hash of the content. So, I'm wondering in terms of the different requirements that you've outlined for the certificates, are there any special characteristics of that use of the certificate versus other exchanges. Is there any reason therefore that there would be differences or is there just sort of one set of NHIM criteria for the certificates?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

No, for a digital certificate to sign an e-mail, no, there's just—any kind of transient data, you could use any certificate to do it. In fact, both NHIM CONNECT and Direct have a requirement for digital signatures because the NHIM CONNECT has the signing of the SAML assertions that are exchanged. So, both of them have the need to use their certificate for digital signatures, but there's nothing unique about a certificate that makes it usable for or for a key that makes it usable for digital signature.

The certificate itself, however, always includes an extension called key usage and some of them have additional key usage. The key usage specifies what the key can be used for. I would expect the standard to include key usage as one of the extensions that are included.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, thank you.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Like with Direct, it needs a key to use for authenticating the recipient. It needs a key for encrypting the content or encrypting keys if it exchanges a key, and it needs a key for the digital signature, but they don't need to be three different keys. It can all be the same thing.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, that was my question, thanks.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Oh, okay. Thank you. Okay, our second recommendation—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Dixie, it's David. I just wanted to make a comment on Jim's question about managing all those trust anchors. The reason that PKI-based models for secure messaging have failed in the past is exactly that reason, is that it's too complicated to make decisions about managing essentially thousands of trust anchors, particular if trust is managed at an individual level.

So, the Direct approach was to create the HISP and essentially outsource the management of the trust model to the HISP. So, somebody still has to make the decision, but it doesn't need to be individual users. You in a sense trust your issuer that they're going to follow whatever appropriate policies have been defined maybe set by this governance model that we'll hear about some time this summer and let them take care of it.

On your PCs, the PC vendor pre-builds in to what's called a browser pack a list of certificates that your browser will trust, and we all trust Microsoft and Firefox and others to assemble the correct set of trustable certificates. In the news last week was the discovery that at least one of those certificates was bad, which is a major compromise to security assumptions of everything. So, you do have to trust somebody to do a good job, but it's the HISP that takes on that burden in Direct. That HISP could be your EMR vendor. It could local HIE. It could be an independent entity, oh, like the ones running those pilots. So, the individual user shouldn't have to think about it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, thank you, David. That's a really good point. It would work just like any kind of controlled environment. I work for SAIC and the bundles of certificates that I trust are put in there by SAIC because they go out and they're like a HISP. They determine that the following are trustable and put it in there and those are the exchanges we can exchange with.

Okay. This is our second recommendation and this is a recommendation to the ONC. All digital certificates that are used by federal agencies like the VA and the DoD, CMS, etc. are required to link back to the Federal Common Policy Framework Certificate Authority. So, the federal government has its own certificate authority, and they must include the assurance level under which the certificate was issued.

So, to go back to Jim's question, in the case of the federal government, they have established rules for who you trust. They have four levels that they defined that basically correspond to the NIST levels of assurance of identity and they include several different kind of flavors of medium assurance for software, hardware and PVI cards, or the smartcards that are used for individual authentication.

Certificates that are used to support exchanges between federal agencies and state agencies have to be issued by a certificate authority that is cross-certified with the Federal Bridge Certificate Authority. So, there's a Federal Bridge Certificate Authority that serves as kind of a linkage between the federal PKI and the non-federal entities.

To enable health exchanges between the Nationwide Health Information Network, we've got to come up with a shorter name for that; exchange in federal health agencies, the Nationwide Health Information Network managed PKI is cross-certified with the Federal Bridge. So, I have this as a picture. This was adapted from the source I have cited there at the bottom, but basically, we have over here; here's the federal PKI and here's the Federal Bridge Certificate Authority. Up here, we have various. We have states like Illinois. We have Department of Justice. We have various PKIs that are these little double certificates. You probably can't see my…. The little double certificates indicate cross-certification. Cross-certification means I sign your certificate and you sign my certificate; so we sign each others.

Over here to the right, we have treasury, various departments of the federal government and they're all cross-certified with this Federal Bridge. Down here on the right, we have the Nationwide Health Information Network managed PKI, which is also cross-certified with Federal Bridge. At the bottom, we have the SAFE-BioPharma Bridge, which is for the pharmaceutical industry, and we have a … Bridge, which is for the aerospace and defense industry. These two at the bottom are both bridges that are non-federal, but they're allowing exchanges with the Federal PKI.

The single certificates, like here, just to fully explain, this is the certificate authority. It's giving out certificates to various entities under it. So, the double certificate is cross-certification; the single is just issue a certificate.

The Direct project, as we just discussed, allows most of this multi-route model that we've discussed at length here in which the certificates are generated by certificate authorities without a common route, such as the HISP that David McCallie just mentioned. Both the Nationwide Health Information Network and Direct users will need to exchange health information with federal health agencies and most specifically, the VA, the largest provider and the largest payer in the nation. So, it's almost inevitable that every Direct user in every Nationwide Health Information Network user is going to need to exchange information with federal agencies.

So, we ask ourselves the question, "How feasible would it be to require that certificates that are used in Direct exchanges be obtained from certificate authorities that are linked to a bridge or a certificate authority that is cross-certified with the Federal Bridge?" So, this would look basically like this where we would have either a Direct Bridge Certificate Authority that would be cross-certified with the Federal Bridge and then all the certificate authorities who were issuing certificates for Direct exchanges would then be cross-certified with the Direct Bridge itself, or you could conceivably have a certificate authority

independent like you do in these other entities that would be cross-certified with the Federal Bridge Certificate Authority.

So, our recommendation that we are presenting for your consideration is a recommendation to ONC and that is to enable Direct users to exchange health information with federal health agencies. The Privacy and Security Workgroup recommends that ONC investigate architectural and operational alternatives for cross-certifying Direct certificate authorities with the Federal Bridge CA including implications on cost, market dynamics and complexity.

John Halamka – Harvard Medical School – Chief Information Officer
So, Dixie, at that point, do you want to stop for discussion on this question?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, so we have David and Wes. I think Wes, you were first.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
For once, I'm not the last person who asks. So, Dixie, what I understand from all the circles and arrows on the drawings, if I am a CA that is allowed to cross-certify with the federal government and I issue a certificate to somebody, let's say Alice just for consistency, from that point one, the federal agencies trust Alice the same as if she had a certificate issued from the Federal Bridge. Is that right?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It depends. The certificate will say—a federal certificate, as one of the earlier slides said, a federal certificate will indicate what Alice had to provide in order to receive that certificate. So, they will trust the certificate, but whether they trust—they will trust the certificate to have been capable of being used in exchanges with the federal government, but you may require different levels of identity validation and that will be part of the certificate. So, yes, you trust the certificate, but you also need to look at and determine your own policy with respect to what level of identity proofing do you require.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So, the federal agency trusts this second CA to provide them honest data to make a policy decision with.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, so now, does that imply that the requirements to become a cross-certifying CA and to maintain that status are fairly strong? I mean what I'm really asking is to what extent does cross-certifying with the federal government narrow down the market for certificate authorities substantially? I mean is it something that can be easily done or is there a $10 million investment in doing the necessary things to be cross-certified with the Federal Bridge?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, that's exactly what we're asking the ONC to look at. We do know, for example, that like VeriSign provides individual certificates free of charge and VeriSign is supposedly cross-certified with the Federal Bridge CA, but that's individual certificates. So, what we don't know or none of our members knew, maybe somebody does, is we don't know the cost for an organization or for a certificate authority, what

the total cost is and that's what we believe is worthwhile, is something the ONC should investigate, but that's exactly the question we're asking, Wes, exactly.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
All right, thanks.

M
And this is a question that I had teed up, which is is that if CMS is going to be a recipient of quality data, how is it if I want to use Direct to send to CMS, which is a simple way for physicians to send data to you, can you trust the integrity and security of that connection? Is this an approach to that? Maybe, unless it costs vat sums of money and is very challenging to maintain.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David. Just to exactly restate that, that was going to be my point, but just to make sure it's really clear is the dilemma that we feel is that in order to have secure communication between non-federal doctors and federal doctors at the VA or whatever, currently you require this cross-certification if you want to strictly follow the rules. But, we were led to believe that that's a fairly expensive and cumbersome step for a certificate authority. Since one of the goals of Direct was to engage as many providers as quickly as possible, that's why we've formulated this as a specific, something that needs to be study. If there's a compromise that has to be made, who makes and how is it set up?

The model will theoretically allow the HISPs to trust the VA with a different certificate than it trusts everybody else. So, you could have a fragmented market, but then you lose the universal addressability goal, that if you have a direct address you can reach it. If we have lots of different partitioned trusts, that breaks that goal. So, I think it's a really important question. Unfortunately, Arien and Doug don't look like they're still here, but I'm sure that word will get back to them. Oh, hey, I didn't see you sitting there. So, we really want to know the answer.

M
Go ahead, Jim.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Dixie, great presentation, great work. I'd like to make a friendly amendment that we ask ONC to estimate the benefits. There will be very large financial benefits to people like the VA and other benefits as well. If we're going to do a cost benefit analysis, that's clearly part of the equation.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It's coming. We will.

John Halamka – Harvard Medical School – Chief Information Officer
And so, at this point, we have a recommendation to ONC really to study. I mean this is not a recommendation to adopt, and so is there any further discussion of the recommendation? Any objection with going forward to issuing this recommendation to ONC and then in a timely fashion, ONC will come back to the committee and say, "Sounds great" or "Yes, for only a trillion dollars you too can have this"? Okay, well, so moved and let us make that recommendation.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Let the record show that I will add, as Jim suggested, the benefits to this slide as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Dixie, Nancy had a comment.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Dixie, Nancy Orvis. I noticed on your slide 15 that you were talking about how the exchanges for the Direct project would most benefit the VA and CMS, but does this certificate recommendation affect anything on the nationwide CONNECT project, or is that not a question because that's another federal benefit that really—our issue was the TRICARE benefit where—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Oh, yes. Yes, I just explicitly called out VA and CMS because that's the largest provider and payer in the United States. Clearly, the Military Health System, SSA exchanges; there are a lot of entities in the federal government that exchange health information with private entities - CDC.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
So, I just wanted to make sure that that would be a huge benefit to American taxpayers because all three of those benefits and four, Social Security, Medicare/Medicaid, the VA and the Military Health System, are benefits that are covered by American taxpayers. We've been trying to look at—that health insurance cost is a cost that Secretary Gates is also trying to keep under control for the military health expenditures.

So, yes, it would benefit a lot of folks, but that exchanges could be between any kind of insurance plan providers and whichever, thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Now Dixie, what I just realized in reviewing your presentation is that we have just approved recommendation two, but we probably should just reflect that you had made some recommendations in your first section as to requirements of certificates and evaluation criteria. We didn't have any objection and discussion, but did you want some formal recognition that we wanted to forward such requirements and evaluation criteria to ONC?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that's why we have chairs.

John Halamka – Harvard Medical School – Chief Information Officer
Very good. Perfect. Well, I was going to get to it by recommendation three, so don't worry. So, recognizing that Dixie presented the characteristics of X.509 certificates, were any of those recommendations in slide ten or the evaluation criteria in slide 11, any discussion that you had or questions you had on those? From my knowledge of digital certificates and management, they seem like very reasonable, straightforward, consistent with industry best practices kind of recommendations. Any objections to also making sure recommendations to ONC?

Okay, Dixie, we have recommendation one and recommendation two approved; on to recommendation three.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I wanted to ask Nancy if she wants any specific changes or was that just for a clarification?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

That was just clarification. I'd have to take that back to my other experts to ask anything more detailed at this point.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, you didn't want me to change anything on the recommendation itself.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
As long as it meets federal law on federal entity PKI and what I would call FISMA, and DoD, that would be fine.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay, thank you. Okay, our third recommendation is a policy question for the HIT Policy Committee and I should mention that what we really would like to send over to the Policy Committee would include those introductory kind of tutorial slides that we had at the beginning at well just so that we can establish a common understanding of what digital certificates are all about before they really go into the issues that we want to bring up.

So, the trust issue is exactly what Jim brought up, Jim Walker brought up a while ago is that the digital certificate can be trusted only to the extent to which users trust the certificate authority and anyone can set themselves up as a CA and issue certificates. Certificates that are used by the Direct project entities may be issued by any CA; so, there's no restriction, and the decision whether to trust a certificate is left up to the communicating entity's trust relationship - do I trust them or do I not? Then the final point is to exchange information with federal entities. The user will need to hold a certificate that was issued by a CA that is trusted by the Federal Bridge CA.

So, those are just the parameters around the basic trust issue that is behind this question for the Policy Committee. The specific question is—well, it's identification of a need. We identify a need for policy and governance around certificate authorities who issue certificates for use in health exchanges such as Direct and that this policy and governance should define a mechanism for establishing the legitimacy and trustworthiness of the certificate authority. The policy and governance also should define a minimum level of trustworthiness for certificate authorities that are issuing certificates for Direct exchanges.

As examples, I pointed out the certification by Web Trust or the European Telecommunication Standards, SI, Institute. Is that sufficient for information exchange, for health information exchange or does the CA need to meet the minimum standard that's defined for a trusted relationship with the Federal Bridge? These are the questions that we would like to send to the Policy Committee. We believe they're policy issues and not technology and not standards.

John Halamka – Harvard Medical School – Chief Information Officer
I think in the process, and this is a Judy/Jodi question, is that if we have questions that we cannot provide standards recommendations without further policy guidance, we submit questions to ONC, we transmit them to the Policy Committee, conceivably assign them to a committee as appropriate there and then get back.

W
Yes

John Halamka – Harvard Medical School – Chief Information Officer

Okay. So, these are very reasonable and valid policy questions. Are there any comments or discussion of those policy questions? Any objections to sending them on to ONC? Okay, well, Dixie, we now have all three of your recommendations endorsed by the committee.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Great. Thank you, all, very much. So, now, shifting gears, the second standard that we were asked to develop requirements for is for entity-level provider directories. Walter is going to give everybody an update on our work in this area. Walter, just tell me when to switch the slides and I'll do that.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thanks, Dixie. I have the control here, so I can move it here. Thank you. Well, Dixie started by showing you a slide that showed the standards development context and the process. She mentioned that we are really testing this new process and this new relationship, I guess, with the SNI framework with both the digital certification recommendations, as well as this new set of recommendations on entity-level provider directory. I'm going to be going through an update on where we are with the process within the workgroup and talk about some of the next steps.

Let me start by bringing you up or reminding you basically of the recommendations that we received from the Health IT Policy Committee regarding entity-level provider directory. We reviewed this, I think, a month or so ago at a previous standards committee meeting, so I'm not going to get into the details. You have it as a reference, but the recommendations from the Policy Committee with respect to entity-level provider directory were around the fact that the content of the ELPD should include this type of information about the entities, demographics, information exchange capabilities, and security information about the entity.

In the next slide, the second set of recommendations were regarding the business model and the operating approach in which the Policy Committee looked at what's the approach that would need to be used in order to establish these ELPDs and the concept was to use an Internet-like model where there's some national coordination, but in a federated approach with certified registers for entities that want to be listed in the entity-level provider directory, some national guidelines, a register reciprocity process in which you just need to link or be part of an entity-level provider directory at a particular level and that will be cross-referenced across the system. So, these were some conceptual elements that we in the Standards Committee, Privacy and Security Workgroup, used as reference.

The next slide talks about some of the other recommendations that were approved by the Policy Committee. That group listed basically the types of entities that would be expected to be listed in the ELPD, a group in four different areas - healthcare provider organizations like hospitals, clinics, nursing homes, other healthcare organizations like health plans, public health agencies; health information organization likes the operators of an HIE, and other organizations. Basically, it's any entity that needs to be listed because there are going to be involved in an information exchange.

Then the recommendations from the Policy Committee included also an expectation of some functionality, basically support Direct exchanges, send and receive, as well as query retrieve, provide basic discoverability of entities, provide basic discoverability of the information exchange capabilities, and then basic discoverability of entity security credentials. Those were the basic elements. Yes?

M
Yes, I have a question. With regard to the folks that would be listed, are these folks that are offering services for exchange? So for example, one could imagine that there is somebody who has demographic and identification information present, but not be able to participate in any of the protocols that might be

listed. So, it's a … position that when it comes to the information exchange services, that they would have to offer at least one of those to get into the registry, or is that they would be entities that you might find and they aren't participating in one of those services?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Well, that's a really good question. I think speaking from the workgroup on the standards side, I think this is policy question as to whether a particular entity that doesn't support a specific type of exchange could be listed or not. I think the expectation from the Policy Committee side based on the recommendation was that, as we said in the fourth bullet, is basically any organization involved in the exchange of health information would be expected to be listed. If they don't have an electronic capability to exchange that information then they're probably not going to be expected to be listed because they don't have that capability.

So I think my understanding at least and my reading on the recommendation from the policy committee was much more specific as to entities that have the capability to exchange information and that I involve in the exchange of information will be the ones listed here. Again, if an organization's a clinic that doesn't have, doesn't support one of those information exchange – none of them basically have any information exchange capability – then the directory will not provide any benefit, basically, to that, because they're not able to exchange electronically.

M
One of the challenges we've had in Massachusetts – I'm sure it's the same in all of your states – is that we don't have 100% electronic health record adoption, but we do have near 100% adoption of fax machines. So we have an entity level provider directory that can list a well-formed URI of some variety – REST, SOAP or whatever – a secure e-mail address that conceivably can be used because we have trust relationships among several entities with certificates that protect the data that goes over the Internet or a fax number. I mean, we could all argue whether or not fax is safe, reliable or secure, but in fact, until we get 100% of EHR adoption having entity level provider directories that are capable of supporting a fax number, it may not be an awful thing.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I was actually thinking – it says on there that you can put in a Web site.

John Halamka – Harvard Medical School – Chief Information Officer
Yes.

M
So it doesn't conform to, perhaps, any of the standards for exchange that we might think about with direct, with connect, or with exchange or whatever, but there's a Web page and if you want to issue a consult, you take the consult, you upload the Word document to their Web site. You fill out the form that they got on the Web site.

The issue is if what it is is a way to find people that use standardized services, there may be a different kind of structure that you would use for that directory, as a directory to find Web services or is it just a Yellow Pages that says here's the name and the other pieces? If you go to this Web page you can upload the information on your Word documents and fill out a form to get a consult.

I guess what I'm trying to do is there's a list of following entities that should be included. My guess is that is not comprehensive and that over time that may change for the people with the organizations that need to be included. So if there's a criteria that can be applied that says, "If you are a medical entity involved in exchange in whatever form, we include you." Or is it an entity that is participating in meaningful use exchange or in standards – whatever it is? I'm just trying to get some clarity around that.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Let me just reply one point. We were just presenting here the recommendations that came from the Policy Committee side. This is a very good question for the policy committee, too. I think one of the purposes or the main purpose of the concept of electronic entity level provided directories was to support electronic exchanges and support direct, exchange and other methods of electronic exchanges. Now, it did not preclude the possibility of expanding it to be much more of a Yellow Page kind of directory that includes basic information about how to communicate to that entity in a non-electronic way. It doesn't preclude that, but the main purpose for the provider directory was to support electronic exchanges, support direct and support exchange and other things.

John Halamka – Harvard Medical School – Chief Information Officer
So on the flight down here, since I had read the U.S. HIT strategic plan I read the New Zealand HIT strategic plan, and they have 99% of all provider entities and individuals listed in their national provider directory, and have since 2005. So I would think sure, it's going to help us with exchange, but as you look at stage two and stage three, we have to do things like provide a list of your entire care team. I'm not quite certain how to provide a list of an entire care team across a community unless I know who the care team is. I could think of it as Yellow Pages that also includes metadata for the exchange of data among other purposes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
This is Dixie. It seems to me that this could be resolved fairly easily since Walter is on the policy committee, is working on the individual level provider directory, and that workgroup won't deliver its recommendation until mid-April. Walter, maybe you could bring this topic up within that workgroup.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Absolutely, Dixie. Yes. I happen to co-chair, actually, the provider directory workgroup on the policy side, so I have made a notation about that and we'll be discussing this week later with that group.

John Halamka – Harvard Medical School – Chief Information Officer
We have several folks who have raised questions, so Nancy?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I almost hate to bring this up, but is there any relationship between the national provider, a taxonomy identifier and what will be in these provider directories?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Well, there is a national provider identifier system at NPI. There's actually a separate taxonomy code set that defines the code specialties for taxonomy, but the NPI, the national provider identifier, could be seen as a source of this type of information. There are several types of sources like that. The NPI, which includes NTT as well as individual providers listed in there, is one of them. There are several other potential sources, certainly. This is not really intended to replace that nor the expectation –

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
My intent was not to ask. I know it's not supposed to replace that. I said one of the issues that we have found on trying to use the national provider database has been that there isn't any enforcement of any syntax on how names are put in there for people over time. They can be Jack Smith, John W. Smith, Johnny Smith, Jack Smith – whatever. One of the problems that we've found when we are trying to check large numbers of providers in our network is if you don't ask for the name the right way it doesn't tell you anything more. It just tells you that's not it and you didn't get it.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Well, that is one of the specific areas of the recommendations that the standards committee workgroup on privacy and security will make on the content of the data that will be expected to be included in the provider directories. It gets to exactly that.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

It's just that I said if we go through this again as we create national provider directories and have never fixed that other issue, we either need to just say they're totally disassociated and come up with something better, but I think it could be an opportunity, let's put it that way. It's an opportunity to say given what we're trying to do with national provider directories now, do we want to go back to the national provider database and maybe clean up syntax and put in some things about how we would prefer people to register themselves? It's a headache.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker. It's probably already obvious, but one of the virtues of the Yellow Pages would be that it could notify a sender if the address, the only address available for a recipient, was a non-secure address.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes.

M
It's, again, maybe stating the obvious, but I find people getting tripped up by the name of this. When it says "entity level provider directory," they assume that it's for providers, but it's providers in the entity sense, not in the individual sense. We keep slipping into language about using it for direct and we say things like, "Find his address" or something. This technically would not help you with that. It will not give you individual addresses. It's a Yellow Pages, not a White Pages.

M
You said that you want to do organization-to-organizational data exchange. Many of us are doing it.

M
It's really just scratching the surface of the problem that we have to solve.

M
Walter, I know we want to get through all your material. There are two other presenters. I think you're going to take about 15 minutes and we do want comment time, so take it through.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I only have a few more slides. This is the fourth slide of the recommendation. This is the one that's specifically from the policy committee. They asked the standards committee to look at identifying technology, vocabulary and content standards that will support the ELTD. That's basically what this recommendation reads.

So we put together these couple of schematics to try to explain in our own minds, basically, and interpret the concept that the policy committee was describing. This particular slide talks about on the left hand side the ELPD registration process, how one would see it, where you see three different ELTD registers, whether they are at a state or regional level or whatever level they are. Behind them on the left you see all the entities that are expected to be part of that register. Then to the right of the register you see the actual ELPD, the directory that the register will generate.

Now, three of those registries, the ELPD's themselves, will then be sending information to the national registry system to basically allow for that exchange and ability to have reciprocity across the system and standardization across the systems.

Then on the right hand side you see the ELPD query and response side. So entity is a hospital, a pharmacy, a clinic submitting a query to the registry system to find a particular entity and then receiving a response back. Conceptually, that was the simplest way to describe, basically, the mechanisms by which this would work.

In the next slide we try to target on okay, so where are the standards required? What is it that the policy committee recommendations asked for standards? You can see here – I'm going to start from the left hand side. The first set of requirements are really a policy level set of requirements around a register

certification process, or ELPD, for entity level provider directories. The ELPD certification itself, guidelines for verification and validation of entries in those ELPD's, register reciprocity – all these elements are more policy level elements than standard level elements.

Then moving along the sequence there, the next one is on the ELPD, which is the bottom box in blue, where we have a first set of standards, standards for ELPD structure and content. I'll talk a little more about it in the next slide.

The next one is the little circle communicating the ELPD and the national registry. There's a standard for the ELPD submission to the national registry of information in the ELPD. Then on the other end, to the right on the screen, you see the message going from the hospital to the registry, so we need a standard for a query and response message from the entity querying the registry and the register responding back.

Then, also, the expectation from the policy committee recommendations was that there was going to be some certification criteria for EHR's to support this ELPD messaging, so we also need to look at certification criteria. Those four blue boxes are basically the scope of our work on the entity level provider directory. A few more words about those boxes. On the ELPD structure and content side, basically we're looking at the standards for the structure and content that will allow the ELPD to support discoverability requirements so the information exchange capabilities, the security credentials, to support the links with ILPD's, the individual level provider directories, because there's expectation that there will be a link between the ELPD and the ILPD's.

The minimum data set is really what will be defined here, the definition of the data elements that include all those elements recommended from the policy side – demographics, information exchange capabilities and security credentials. On the submission to the national registry, again, this is primarily a published and post-protocol, basically, a message that goes from the ELPD to the national registry system.

Then the other two areas of standards are the ELPD query, as I mentioned, the querying language and the messaging going from the entity that is looking for another entity in the ELPD and receiving a response back and then the EHR certifications, standards and criteria that would create the functional requirement on an EHR to support the submission and exchange of messages with entity level provider directories. So those are the four areas we're focusing our attention on the entity level provider directory side.

So where are we today? We started discussions. Of course, you've seen the last couple of months we've focused significantly on the digital certificate work, so now we're going to change our gear and our attention and look at the provider directories as our primary target over the next couple months. We reviewed testimony back in September of last year. The policy committee's information exchange workgroup under which the provider directory resides held a full day of hearings on provider directory. This is where the recommendations, basically, from the testifiers came. The first priority on provider directories should be at a thin layer of discoverability functionality at the entity level, not at the clinician or individual level. That will be a second order or priority.

So we looked at the testimony. We are reviewing the work that is being done in existing implementations, like the NwHIN requirements for directory services, the Vermont Health Information Exchange, the direct project, the VA. We have heard testimony at our workgroup from those organizations and we will be hearing additional testimony from others, more of the work that is being done in the standard development arena on provider directories. A lot of work is being done right now by a number of standard development groups, so we want to hear about those as well.

So that's where we are today. We also wanted to point out we have heard, basically, that the ILPD recommendations, the recommendations from the individual level provider directory, will be presented by the information exchange workgroup to the policy committee April 13th We expect that after that we will have a final set of recommendations on ILPD. The thought was that the timing is appropriate and we're sort of transitioning from the digital certificate work to the provider directory work. We will now have both the entity level provider directory recommendations as well as the individual level provider directory.

Recognizing the interdependencies and the linkages between the two, we requested to the standards committee leadership here to sort of delay that development of the recommendations. Originally we were going to have recommendations on ELPD first coming out very quickly and then in a separate sequential process develop the recommendations on the ILPD, but we thought it would make more sense now that the timing's right to bring the two together and work over the next couple of months again to prepare and deliver recommendations for both ELPD and ILPD to the standards committee, which we expect then to be delivered by May of this year.

That's where we are today. I don't know if there are any more questions about the process. Dixie, I don't know if you have any other comments that you want to make.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I don't think there are any other comments. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Of course, given that the two co-chairs of this committee actually have no authority, we deferred to the fine folks at ONC and said, "Would it be okay if we aligned all of this package for the main meeting?" We just, of course, want to make sure your timelines are being met. Given the interrelationship between the ELPD and the ILPD, it certainly makes sense to have a common set of standards that would be used across entities and individuals, and we'll have that for you by May. If that doesn't work, please let us know. We want to make sure that we don't come up with one set of standards today that have be radically changed in 30 days, as the policy comes out on April 13th. Arien looks concerned.

Arien Malec – RelayHealth – VP, Product Management
Yes. If we think that the standards are going to be cut and dry, that's a reasonable timeline. The conceptual picture I think makes a lot of sense. What standards do you pick? I think the experience, I think many of the folks around this room and in the community have tried different things and have had varying levels of success. The concern I have about waiting for May is that if we want to get anything in an MPRM we have a microslice of time to actually do the upfront bidding work. That's the only timeline concern that I have, how cut and dry we think picking the standard is and how much time, how much more lead time do we need to go through – well, there are three different standards in this area, there's an HL7B3 standard, there's an IT standard, people have done varying bits of each, and we need to get all that on the table and figure out, regardless of how we'd wind up ILPD and ELPD, what the appropriate standards are.

M
At the risk of potential rework then, can we assume that it's likely to become logical that ILPD and ELPD are inherently related and need to be harmonized and also support the use cases that are envisioned in the subsequent stages of meaningful use?

Arien Malec – RelayHealth – VP, Product Management
I think that would be a reasonable assumption to start with, yes.

M
I think we should proceed with that process so we can expedite the timeline and correct as necessary. John?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Very, very reasonable. Obviously, you guys have already begun to specify the potential standards – as you said, HL3B7, IHE, there have been some proprietary SOAP and LDAP kinds. There are three or four different variations. Get those out on the table. We get our recommendations on the 13th. Make sure that those policy recommendations align generally with the standards you've chosen, and as rapid as we can, try to achieve the consensus on our recommendation.

Wes Rishel
Walter, slides 26 and 27, 27 calls for an electronic exchange between an EHR and the registry. Twenty-six more or less implies that that's the means of operation for everybody who's accessing the registry. I want to be sure we are not doing exclusion by omission here in the sense that it may be that there are Web-based ways for users to access the directory rather than through intermediate information system. There's probably no need for a standard at this point. I just want to make sure that we're not excluding that model and all of the business implications of that model at this point in the process.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Good point. Yes. I don't see that we are expected to preclude or exclude any particular …

John Halamka – Harvard Medical School – Chief Information Officer
Mark?

Marc Overhage – Regenstrief – Director
Yes, just two quick things. One, Walter, sometimes I get lost in your eloquent descriptions, so is the model that you're going to describe the requirements and then stack options against the requirements and that's what we're going to hear in April?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. Basically, if you look at what we did with digital certificates, where we made recommendations on requirements and then recommendations on validation criteria, that's exactly the kind of thing that we would bring back.

Marc Overhage – Regenstrief – Director
So assuming that model, the real question then is it seems to me that this is a good example of where we don't want to get too focused on the standards. We may want to think about the process that's involved and that might end up being an important requirement because frankly, this sounds like standing up a whole bunch of new stuff that's going to take a very long time and lots of procedure and process. I don't know how you factor that in, but it seems like the time boxing might lead us to a different conclusion than standards perfection.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Sure. I think it's important to recognize also that the policy committee recommendations, not all of them really apply to the standards group. A number of the policy committee recommendations are really policy aspects that are not truly the responsibility, if you will, of the standards committee. The standards committee workgroup on privacy and security tries to define the scope of where we would be focusing our attention with respect to standards that apply to provider directories, but the operational aspects of it, I mean the way in which this will operate ultimately and how it will happen from a policy perspective, that's really not –

John Halamka – Harvard Medical School – Chief Information Officer
My plea is that we not do that in isolation. Those are no independent decisions.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
They're not. I mean, they are already sort of direction from the policy committee with respect to the constraints around how operationally this would work. That's the basis for where we're focusing our attention on the standards side.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
This is Dixie. I agree with Mark. I think that digital certificates were pretty straightforward. I don't think this is nearly as straightforward. It kind of bothers me that from Arien's comment it sounded like we're trying to put this in stage two meaningful use or something. You know, we have large organizations, the VA being the one that instantly comes to mind, that don't have directories already. I mean, the point that Mark is making is significant. This is a different way of doing things; it's not just a standard for doing something we know we have to do.

John Halamka – Harvard Medical School – Chief Information Officer
Let me give you an example of how, Dixie, I think we could include some kind of transactions of this type in a stage two. So it turns out that in Massachusetts we have built an entity level provider directory, but we've embedded it and it has absolutely no standards that any other state would ever use. For us to retrofit that database with a set of different kinds of exchanges, whether they're HL7B3 or IHE or LDAP or whatever is actually trivial work. So we could probably do a demonstration of how a set of standards could read a database of providers. Now, it's not going to be national and it's not going to be complete, but we could do a demonstration.

So what I'd hope we'd do is at least come forward with a set of recommendations so we don't see every one of our 50 HIE's developing 50 different provider directory front ends. That'll at least get us on that right trajectory.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Exactly. I think who is building this or who is really going to do this is the HIE's. The HIE's, the 50-plus HIE's, are expected to, in some cases required to, develop a provider directory for the HIE in the state. They're clamoring for some guidance and some assistance in terms of defining the standards that will be used in order to be able to build it once and be able to interoperate with the others across the border of the next set.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
If you go back to the EHR stage two conversation, what we would want for an HER certification is just being able to query it, right? A standard for building an entity level provider directory, if that's something to be built by HIE's, then to me, that doesn't belong in a stage two meaningful use scenario other than being able to query it.

John Halamka – Harvard Medical School – Chief Information Officer
That was what I was suggesting, Dixie, a capacity to issue a query to a directory somewhere. It could be local, it could be state, it could be regional, it could be whatever. Arien?

Arien Malec – RelayHealth – VP, Product Management
You just asked the very same question. If I'm understanding really the charge it is, I think states are looking for the "What do I do?" The "What do I do?" does involve all the aspects of the picture that you drew.

With respect to EHR certification, there's a much narrower subset that we'd need to focus on for the stage two timeline, which is just the query retrieve.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I brought up this slide number 27 and you can see on the right hand side, that is the only place where certification criteria applies. The other three blue boxes have really nothing to do I guess with that respect, with the meaningful use aspect of the stage two requirements.

Arien Malec – RelayHealth – VP, Product Management
There's a potential short-term project that wouldn't make the states upset because they're not getting the full level of guidance that they're looking for but would at least allow us to meet a stage two meaningful use timeline.

John Halamka – Harvard Medical School – Chief Information Officer
Annually assemble the provider directories but have a standard query technique, and that's going to be a whole lot better than 50 different query techniques.

Well, very good. Last comment, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I know we've talked about this in the committee some, but it just kind of reinforced today hearing the discussion about certificates and the discoverability of certificates in the same conversation as the registry. It would be nice if those could be piggybacked in some way. In order to communicate securely you have to discover the public key of the provider. A way to discover the public key of the provider, a way to discover the provider, it would be silly to build two separate models that accomplish essentially the same thing – one is what's in the certificate and one is the key in the certificate, the name on the certificate versus the key on the certificate. It sure would be nice to solve that with one model.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
That's an excellent point. I mean, given the fact that we just finished the process of the … certificates … recommendation, I think it's a perfect way to focus on the provider directories but bring in the elements that are related to the certificates into the provider directory discussion.

John Halamka – Harvard Medical School – Chief Information Officer
Boy, a rich discussion and as we've talked about with the keying up of our work plans for the next several months, certainly by May we'll seek to have the granular standards that would at least be used for query. We hopefully can get those decided rapidly since you guys will have them as necessary and work on all these other aspects.

So with that, should we turn it over to Jamie and hear your report on the all-day device hearings from yesterday, which I understand were quite successful? Many presentations and Jaime will synthesize into a couple of key ideas some of the lessons that he heard from yesterday.

Jaime Ferguson – Kaiser Permanente – Executive Directory HIT Strategy & Policy
Thanks. So as John just said – I have no slides for this – we did have a full eight hours of panel presentations and committee discussion yesterday here in this room, covering a very broad set of issues having to do with the possible inclusion of device-related measures of standards in stages two and/or three of meaningful use. So what I'm going to do is I'm going to attempt to synthesize that down into just a few themes of what we heard. Several of the folks in the room here on the committee were also here all day yesterday and I urge them to add to this.

Some of the themes that we heard were that consumers and patients and differentiating. We had a very good set of definitions differentiating consumers from patients. The consumers and patients need interoperability with regard to devices to be made cheap and easy, both in order to drive patient compliance and to actually achieve the improved outcome that we heard some very dramatic evidence of, in some cases such as diabetes management, using home monitoring devices.

We also heard from the consumer and patient perspective that the biggest problem is clearly the last mile connectivity and setup of the remote device in the local environment to connect to wherever it's going to connect to. We heard several different stories about different approaches for in-home setup. No clear consensus emerged on how to facilitate solutions to that barrier.

We also heard that middleware and data intermediaries are both necessary and will be with us for the foreseeable future. We did have some panelists who said we need to go for direct plug-and-play connectivity between the devices and the EHR, but the overwhelming sense of the day was that middleware and intermediaries of various kinds are a necessary evil and don't see really any way around that for the foreseeable future.

We heard a lot about the provider perspective, both sets of problems as well as benefits from the provider perspective, focusing again on providers who may seek the meaningful use incentives. They found a number of different kinds, sort of categories or classifications of problems. We certainly heard about problems updating device security without having adequate assurance on the provider side of the patient safety, approval of those updates, although we also had FDA in the room saying that although it's a manufacturer responsibility, providers can just apply the patches. Then, of course, the providers really weren't responsible for assuring the patient safety in that case, taking on that manufacturer responsibility.

We heard a lot of provider issues related to non-standard vocabulary. We also heard that there's no standard technology on the EHR side to receive and hold device source data. That was another barrier from the provider perspective.

We heard a whole set of problems around payments and incentives. Sometimes there's no reimbursement for the device used. In fact, seven different panelists in both written and verbal testimonies cited business model concerns as reasons for the lack of standardized interoperability. The committee was asked multiple times to find ways to align manufacturer incentives with the improvements in outcomes that can result from the use of both clinical and consumer devices with EHR's in a coordinated approach to care.

We also were requested multiple times to seek reimbursement for tele-health. Those issues certainly came up.

A couple of other issues from the provider side. We heard very strong evidence that there are problems that providers have getting all the data from devices. Manufacturers typically only allow or have setups that allow for a subset of data from the device to be made available to the ERH, but the providers generally want all the data all the time.

Finally, sort of in this category, I think assuring the remote patient identity is correct was perhaps the top problem for remote devices. Patient ID and patient ID correlation back to the provider setting was the top issue I think for the remote devices.

We also heard a lot about truly great benefits from the provider perspective. Providers are seeing a lot of value in partnership with the care team, where the partnership is strengthened with the patient through the use of devices in a variety of different programs. We heard evidence of, as I mentioned, great improvement in outcomes as well as lower cost, lower readmission rates as well as lower admission rates. A lot of very dramatic benefits from the use of, particularly, home monitoring.

We also heard from a number of EHR vendors and the EHR vendor association that the vendors, for whatever set of reasons, are not able or are not focused on establishing end-to-end interoperability with all the devices, but rather, they're focused on establishing interoperability to and from the data intermediaries. This is essentially the IHE PCD approach of ensuring that data can be sent back to the EHR from the intermediary but leaving the communications from the device to the intermediary up to the marketplace to resolve.

There were just a few, a very small number, of consumer devices that do have end-to-end interoperability relatively well assured through the continua specification for consumer-oriented devices. They have continuous certification. Then on the other hand, we heard concerns about having basically a vendor-run certification process as opposed to sort of the neutral third party approach that we have for EHR certification.

I think then in terms of some of the next steps, the work group plans to convene to consider this input. I mean, this just happened yesterday, so I haven't even typed up my notes or anything like that. I think we expect to consider some possible recommendations for stage three, but almost certainly not for stage two. We heard, I think, very clearly that stage two is premature for this. At the same time, while it may be possible to identify a few inpatient or ambulatory use cases and a few – when I say few, maybe two or three – use cases in devices for stage three and the same in terms of remote or home monitoring, there was I think a very strong sense through the day that it would be highly desirable to set the direction for those standards in stage two even though the requirement would not be until stage three to give the market appropriate lead time to build in those interoperability requirements. This gets back to the business model issue that I mentioned, where the alignment of incentives for the manufacturers isn't there today, but given that amount of lead time, that was thought to be something that could help to mitigate that problem.

I think then the best case, if you will, is that the work group may end up coming back to the committee here identifying a few devices, a few use cases, a few standards that are mature and easy to use that we might want to come back and recommend for inclusion in stage three but have some mechanism for giving notice to the market that this is to be included so that there's a longer lead time for development.

Before taking cards up from others, maybe I can ask those other committee members who were here yesterday if you want to add to that.

Liz Johnson, Tenet Healthcare, Co-Chair
This is Liz Johnson. I would just say - Jaime did a nice job of summarizing – it was very, very clear that the value of the data that could be gotten from the biomedical devices is desirable and needed for better clinical outcomes. If we're going to have care across the continuum, it has to happen, but we're not ready. I thought it an astute observation that we need to start now so we will be there in time rather than putting an expectation out there that people can't meet and then listening and failing to do so. I thought the hearing was very well spent time and certainly want to acknowledge the panels. Their work and input was excellent.

John Halamka – Harvard Medical School – Chief Information Officer
I just want to give you guys an example of a device I have at home. I think it's instructive to all these lessons learned. I told you about my Wi-Fi based electronic bathroom scale before made by Withings, a French company. When I step on it, it measures my weight, my body mass index, my percentage of body fat and does a restful exchange using JSON rather than XML to an intermediary site operated by the scale manufacturer, which then provides a Web-based dashboard that allows me to forward the data to Google Health, to a URI of my choice, to my Twitter account if I so wish, to an FMTP address of my choice. In fact, if we look at some of your themes, a Web-based interface that gives me a set of places I can forward the data by clicking a button, typing a URL or typing an e-mail address, consumers and patients can use that quite easily.

Cheap. Literally, I put it in the bathroom, I turned it on, it bonded via WEP to my local wireless access point and began transmitting the data. Very, very straightforward. The last mile issue was do you have a Wi-Fi access point in the house? The patient identity issue is solved in a very interesting way. It is that the very first time it sees the weight of any person in the household it predicts you are unlikely to gain 50 pounds overnight, so that must be a separate entity. Every time it says the variation of weight is more than I would logically expect a human to have it says "This is an unknown entity. Please specify the initials of this entity." So you could have a dozen people in the household and the only confusion would be if everyone weighed within a few ounces of each other. So the identity problem, it's not perfect, but it's solved.

So these things are solvable, but the problem is, if the company goes out of business, it is a useless device. Wouldn't you love to be able to tell the device to use direct to go to the location of my choice from the device over Wi-Fi instead of through an intermediary that is a proprietary intermediary?

Jaime Ferguson – Kaiser Permanente – Executive Directory HIT Strategy & Policy
One thing I'll just add is that because we did focus on the complete range of different kinds of devices that might potentially be included in meaningful use, it was just a very, very broad discussion. I think sometimes people have to switch gears as you go through the day because of the wide variety of different use cases that we were talking about, some of which were in that class, but I would say more of which had to do with the use of more traditionally regulated class two, class three devices in clinical and inpatient settings.

Liz Johnson, Tenet Healthcare, Co-Chair
… as a physician have acted on that information had it been added to your acute care record in your hospital and you are a CHF … or whatever. Is that the question we got asked?

John Halamka – Harvard Medical School – Chief Information Officer

Not involving a CHF patient. If there was a weight that went up by five pounds in 24 hours, absolutely.

Jaime Ferguson – Kaiser Permanente – Executive Directory HIT Strategy & Policy
I appreciate everyone who put the effort into the hearing, and the business case also supported it. Right now, this is one of the exciting things about the forthcoming ACO rags, that it creates a business rationale in which that triangulation on the patient's physiologic input and then care providers, if they're separate entities, are in receipt and act on that information. In the current world, the fee-for-service limitation is that may violate, actually, … and a number of other things.

We have a little bit of a press for time, but a number of cards are up, so let's go around the room and take those. We'll go Wes, Jim and Stand.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It's Wes Rishel. I just want to say that there are a number of things that John does that I wouldn't do. Tweeting my weight is high on the list. Adding to Jaime's comments, which I thought was a wonderful job of organizing this stuff, if there was on additional take-away about patient ID, there is extreme concern that it not be done in the middleware, that it somehow be done in the instrument. Some of the issues related to patients who are in transport, in the hospital and are now being monitored through Wi-Fi and things like that. That's an area that if we want to address it has a pretty long lead time, has jurisdictional issues with the FDA and all kinds of stuff. The notion that there could be some way, standard of getting patient ID into an instrument that was an efficient workflow and then could be in the data stream I think was very concerning to a number of people.

I just want to comment that there's an obvious conflict between two requirements we had. One was all the data and the other is standards. They were really wanting to look at data elements that indicate whether there is an artifact in the standard, that they're sort of sensor-specific and things like that. The more complexity, the less likely it is to standardize. To the extent we do anything, we may want to look at standardizing the data that clinically needs to go into the EHR rather than the full set of data.

The other comment – and I may have misunderstood that, so you guys can verify – is these intermediate systems are MDDS's by the FDA.

Jaime Ferguson – Kaiser Permanente – Executive Directory HIT Strategy & Policy
I think some of the intermediaries are MDDS's that basically don't do anything with the data but transmit it. Others perform aggregation, normalization, translation and other functions, so some of them would be class one, but some of the intermediaries –

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
What I really wanted to say was the ones that do anything like compress, take the best reading, anything like that, that don't pass all the data through, will come under substantially more enforcement in 2017 under the FDA, including such systems underwritten by hospitals. That I think is worth noting. I don't know that it's an action item for us.

Jaime Ferguson – Kaiser Permanente – Executive Directory HIT Strategy & Policy
Let me just echo the last thing that Wes said, because one of the things that came up just towards the end of the day when we met with the FDA on their unique device identification proposed rule that they're working on is that the combination of the UDI, which requires a structured product label to be created by the manufacturer of that data intermediary, which is basically a piece of interface, software in most cases, any hospital or clinician office that even configures a vendor-supplied interface may become, under the FDA MDDS rule, a manufacturer of that data intermediary as a device. Therefore, they have to have a quality system under the FDA rules for that, but they also have to have the ability to generate the structured product label, to register it in the FDA's unique device identifier database, and that is an issue for the implementers of EHR technology in meaningful use that could become very significant. That would be basically in the penalty phase of meaningful use because their timeline for these devices is probably longer than the incentives period.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thank you, Jaime. That was great. Jim Walker. So you said providers want all the data all the time. Did that strike you as a misunderstanding of how data can feed into –

Jaime Ferguson – Kaiser Permanente – Executive Directory HIT Strategy & Policy
I think what that really means is that each provider or provider organization wants to be able to apply their own filters to the data that could potentially be generated by the device and not have basically a manufacturer preset filter that says that there are a variety of characteristics about the device or patient data from the device that are not transmitted.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
One of the things that struck me from the conversation – and this sort of distilled into me after a lot of the meetings yesterday – we've had, actually, adequate if not good standards in the past that were not adopted. I think we need to focus on why that is and how we change the motivation to make it successful. We had IEEE1073 which actually was an adequate standard. Intermountain Healthcare actually implemented that. It worked well, but there was no adoption. Some of the barriers to that were discussed in that there was basically no financial motivation for the manufacturers to adhere to that standard. So we need to be a little careful now that we don't launch into creating new standards without an understanding of how those would actually be implemented and whether there would be a business case and a motivation to use them.

I thought there was a nice clarification also that Wes brought up yesterday. It goes along with that intermediaries are necessary. I think we all agreed, but I think what Wes clarified was that those functions need to be performed, but in fact, the intermediary could be in the electronic medical records system or it could actually be in the device itself so they're a set of functions. We shouldn't think that we're mandating that there be an independent company piece that has to provide that intermediary.

The third one just came up today when John, did it send the LOINC code?

John Halamka – Harvard Medical School – Chief Information Officer
No.

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No. So it's good for reading, but automatic incorporation into your electronic medical record would have fallen short.

Jonathan Perlin – Hospital Corporation of America – CMO & President I think a terrific presentation and capsulation of hearing lots of good points. Stan, I think your point is particularly well taken, that standards without the compelling business case behind them is not going to move us forward. I think there are a number of things that do create to draw some evolution of healthcare. Others are intrinsic to the work of the policy committee and ONC further out.

What's interesting is that the situation – I think John Halamka described it – is a terrific example of the breadth of the ecosystem and the devices. It's just terrific that you have encouraged the inclusion of the devices as healthcare evolves … continuity of care across environments. It's interesting. A project that we're working on, you don't have to look too far to look at the lack of continuity. It's striking that the average American now is on track for cumulatively 10 CT's in their lifetime, which is, frankly, the amount of radiation exposure that is on the same level as Hiroshima suburbanites. It's absolutely stunning.

On the other hand, there is not a mechanism currently to aggregate the cumulative radiation exposure. While there's these partial standards, the business and policy case doesn't create a draw for that. Whether it's in traditional environments or an expansion of environments, that ecosystem is broad. We look forward to the circle with both the policy committee outside of ONC as well as the draw that these activities provide. I certainly hope to proffer standards that support that evolution. Thank you very, very much for that.

We have one last area before we go to public comment. I appreciate the work that Liz Johnson and Judy Murphy are doing with the implementation of the workgroup. I think we touched on descripting at the outset, but why don't you bring us up to date on the activities with the implementation of the workgroup?

Judy Murphy – Aurora Health Care – Vice President of Applications
Sure. This is Judy Murphy. I'll get started and then ask Liz to chime in.

Basically, we are at kind of a turning point in the implementation workgroup. We reported at our hearing at the last meeting and now we're really turning our attention to the certification process. So we'll be looking at our membership and probably revising that, tightening it up a little bit with probably less members, then creating a work plan really for the next nine months. That work plan is really going to consist of a current state assessment of the certification process and the testing scripts and then a future state, if you will, recommendation for that. We haven't talked through that whole process yet, but it will probably consist of some kind of surveying and input from the general public as well as a hearing maybe this summer.

Liz Johnson, Tenet Healthcare, Co-Chair
The only thing I would add to that is we obviously want to be looking toward meaningful use stage two. We've learned from our previous experience, so we want to take advantage of that and reflect that in our plan, which we'll be back to descript with.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any questions or comments for the implementation workgroup ? John, anything you'd like to?

John Halamka – Harvard Medical School – Chief Information Officer
I think we very early in the meeting described some of the challenges that we've all encountered as we've gone through certification, meaningful use such as "or" really means "and." You want to have all of the aspects of your criteria for certification be easily demonstrable and measureable. You want to make sure that the medications in the scripts are actually prescribable. Hopefully we would be clear about such things as modular and inheritance, because I went through certification twice and actually had to demonstrate everything twice even though it had previously certified because it wasn't clear how you inherit modular certification.

Quality, we've talked about at this meeting. Making sure we have the right testing tools to validate before certification that things are actually working.

One of the things Farzad mentioned to me – this is an interesting idea – what if the certification process was what he would call a linked sequence of testing? I enter a patient – Mary Smith. I then enter an order on that patient. As part of entering that order there is a drug-drug interaction. The data from the order goes into the registry for which a quality measure results. That is, it is one continuously linked set of activities rather than 27 different scripts that you may not, in fact, have crisp, clear data entry from end-to-end.

These are the kinds of issues that will be discussed.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think those are terrific comments and I appreciate the implementation workgroup taking on this sort of frame for those discussions. There's nothing like the real world of experience to test and refine the process to bring back the insights that that process of using scripts really yields.

A full meeting. A lot of activity. I think the suggestion, John Halamka, that you made that we hold ourselves to a script, what … in each of the months ahead? We'll work closely with ONC to sort of tee up focal areas for each of the subsequent meetings.

A broad-ranging discussion today. I want to thank Farzad Mostashari and Doug Fridsma for the terrific opening discussion about the next scope of activities and all the other presenters and participants. Subsequently, as we move to the public comment period, John, I'd just tell you that if I accidentally stand on my wife's exercise program on the Wii, it does not have the logic to recognize that she hasn't gained some number of pounds, it just goes, "Argh." What a potential when there are standards that even ubiquitous devices might be part of a care continuum.

Let us then transition to the public commentary. Judy, I will turn it to you to take the …

Judy Sparrow – Office of the National Coordinator – Executive Director
Anybody in the room who cares to make a comment, let me just tell people on the phone, if you're on the phone pres star '1.' If you're on your computer you need to dial 1-877-705-6006. Please identify yourself. Carol?

Carol Bickford – American Nurses Association
Carol Bickford, the American Nurses Association. I have two comments. One, the clinical quality workgroup that's being stood up is glaringly missing some registered nurse participation. I've already talked to James Walker about that as being something to think about in conjunction, perhaps, with your long-term care representative.

The second is in relation to the privacy and security workgroups report, where they identified on slide 27 where the standards need to be inserted. Based on the discussion about the MPI integrity of the data and the quality, it would seem to me there needs to be some standards initiatives surrounding the ELPD national registry system if something is stood up in that arena. There are the standards recommended for the development of the structure and content and then also for the registry submission, but it seems that that's a big missing piece that if it's going to be stood up, that it includes some standards.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Carol. Robin Raiford?

Robin Raiford – Allscripts – Executive Director, Federal Affairs
Hello. It's Robin Raiford from Allscripts. I just wanted to give a contribution of some work that I had done that seemed to perhaps be meaningful to the discussion in that I've torn into the 113 national quality form measures and put them all into one and tried to find a common thread of what was out there since we don't know what is stage two and stage three, to share that with the group.

To keep under my three minutes, I did send a written copy to Judy Sparrow to send out to the committee, but in that Zip file for the 113 quality measures, there are 450 files. Of that, I pulled into the Excel to find out what's the common thread and there were actually, if you pull out diagnosis, medication, labs and results, because for the most part those are coded in the EHR, it actually turns out to be 15 concept categories that are in there that include about 342 I counted in the concepts. In that, there are 2,600 unique descriptors that are in there that get a little daunting, to Carol's point as well, about including a nurse in the quality measures.

Some of it gets to be to the point of a little bit crazy in that they're all obviously standardized vocabulary into SNOWMED. A lot of these things which might be charted today are in what would be a drop-down list that could be in an EMAR, an alert and observation structured note or an order, and in that drop-down needed to accommodate SNOWMED, which oh by the way is 255 characters, and some of these lists were quite large in that there are 114 ways to describe tobacco use, non-use or cessation for tobacco. There are 88 ways to describe a cough. There are 55 ways to describe sleep disruption.

Now, I wouldn't want to be the nurse who's walking into the guy who has sleep disruption and fly open this list of 55 and decide which one it is, where they'll describe it and then you have the nurse who's kind of in a hurry trying to do a nursing assessment or whatever. When I ran this by our quality folks, they thought it would be difficult that the people wouldn't go through that list of 55; you'd start seeing a lot of people trending the first four or five because they were there. Like a school. You could say a kid went to school. There were 20 kinds of school. Was it an accredited school, a boarding school? Probably nobody went to Montessori because that was down at the bottom, for where it is. I think we're getting very close to that line of what kind of questioning the patient is going to tolerate.

The other one that's here, and I'm probably at the end of my three minutes here, was the idea that we now need to start capturing – to the point about the exclusion that's been brought up – the negation rational for why didn't you do something? It's no longer we did it because the patient refused; there are 63 coded reasons why you would not do something or follow a standard or where you've … alert. Hopefully that'll make more sense when you see the copy that I sent to Judy.

Thanks for your time.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Robin. Gary?

Gary Dickinson – CentriHealth – Consultant
Hello. Gary Dickinson, a consultant representing CentriHealth. Two areas of significant concern to me, one of which was discussed this morning in the context of Doug's remarks in the sense that interoperability – we're focused on interoperability only and not internal representation. It seems to me that we have big problem there because what we really want is the clinician to be able to say this is what I saw on my screen, this is what I accepted. When that goes into internal form in that source system, that it can be reproduced the way that they saw it. Then when it goes across the interface, if it goes through an intermediary, who knows what happens to it as it gets translated and recoded from the originating system to an intermediary, to an ultimate internal form on a receiving system, and then ultimately displayed to the clinician on either side? What does it end up looking like? It's really that end-to-end continuum that gets into our issues of repudiation.

If the author could repudiate what shows up on that ultimate screen, then we have a huge problem with this. That's why we need to look at interoperability not as a point-to-point phenomenon but ultimately end-to-end. What did it start out like, what did it end up like? The internal representation is in there and we can't ignore it. I think that's one area of major concern.

The other thing is I went to … last month and discovered that there are a number of systems that now claim to be complete EHR's. Under the terms of the regulation, complete EHR's simply have to meet this set of criteria. Well, as all of us know, ONC was active in promoting the certification process from 2006 until 2009 that, in fact, raised the bar rather high for certification of EHR systems. In fact, when this group came in, that certification process essentially went away as being officially approved by ONC. Now we have another set of criteria which had … little to do with the original set of criteria, but the bar has been set way down here. Yet, we have people claiming to be complete EHR systems based on the new criteria that simply aren't even close to what would have been required in 2009 for an EHR system under the ONC promulgated certification criteria.

So I think we have a huge problem. I think it's a major disservice to the industry not only from the standpoint that we are recommending that physicians go out and buy these certified systems but that they don't even meet the requirements that we had in 2009. When the question was raised on the certification at the town hall at … "Well, we'll get back to that." So it's kind of like well, maybe in five or six years we're going to get back to where we were in 2009. To me, that's a huge problem.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Gary. We have no more comments. I'll turn it back to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
John, anything?

John Halamka – Harvard Medical School – Chief Information Officer
No. I just think that we do have quite a lot of work ahead. I want to make sure that we get you all the detail that you need to write wise and thoughtful regulations because we will all have to live with the work product. So wasn't it Microsoft that coined the term, "We have to eat our own dog food?" If that's not motivation to work hard over the next six months, what is?

Jonathan Perlin – Hospital Corporation of America – CMO & President
What else to close with than bon appétit. Thank you all very much.